SCHEDULING STATUS: S4

DROVELIS 3 mg/14,2 mg film-coated tablets

drospirenone / estetrol

Contains sugar (each pink active tablet contains 40 mg lactose monohydrate and each white placebo tablet contains 68 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking DROVELIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DROVELIS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DROVELIS is and what it is used for

DROVELIS is a contraceptive pill that is used to prevent pregnancy.

- The 24 pink film-coated tablets are active tablets that contain a small amount of two different female hormones, namely estetrol and drospirenone.
- The 4 white film-coated tablets are inactive tablets that do not contain hormones and are called placebo tablets.
- Contraceptive pills that contain two different hormones, like DROVELIS, are called ‘combination’ or ‘combined’ pills. They work together to prevent ovulation (release of an egg from the ovary) and to reduce the chance of any released egg being fertilised and making you pregnant.

2. What you need to know before you take DROVELIS

General notes

Before your start taking DROVELIS, you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see section 2 ‘Blood clots’.

Before you can begin taking DROVELIS, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop taking the pill, or where the reliability of the pill may be decreased. In such situations, you should not have sexual intercourse or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because the pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

DROVELIS, like other hormonal contraceptives, does not prevent against human immunodeficiency virus (HIV) infection (acquired immunodeficiency syndrome, AIDS) or any other sexually transmitted disease.

Do not take DROVELIS
You should not take DROVELIS if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.
- if you are hypersensitive (allergic) to estetrol or drospirenone or any of the other ingredients of DROVELIS (listed in section 6).
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, factor V Leiden or antiphospholipid antibodies
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots')
- if you have ever had a heart attack or a stroke
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms)
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called 'migraine with aura'
- if you have (or have ever had) a tumour in the liver (benign or malignant)
- if you have (or have ever had) a liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina

If any of these conditions appear for the first time while using DROVELIS, stop taking it immediately and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also 'General notes' in section 2 above.

Warnings and precautions
Talk to your doctor or pharmacist before taking DROVELIS.

When should you contact your doctor?

Seek urgent medical attention
- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below).

For a description of the symptoms of these serious side effects please go to 'How to recognise a blood clot'.

Tell your doctor if any of the following conditions apply to you
If the condition develops, or gets worse while you are taking DROVELIS, you should also tell your doctor:
- if a close relative has or has ever had breast cancer
- if you have hereditary angioedema. Medicines containing oestrogens may induce or worsen symptoms of angioedema. See your doctor immediately if you experience symptoms of

angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing.
- if you have liver disease or gallbladder disease
- if you have diabetes
- if you have depression
- if you have epilepsy (see section 2 'Other medicines and DROVELIS')
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE – a disease affecting your natural defence system)
- if you have haemolytic uraemic syndrome (HUS – a disorder of blood clotting causing failure of the kidneys)
- if you have sickle cell anaemia (an inherited disease of the red blood cells)
- if you have elevated levels of fat in the blood (hypertriglyceridemia) or a positive family history for this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas)
- if you need an operation, or you are off your feet for a long time (see section 2 'Blood clots')
- if you have just given birth, you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking DROVELIS
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you have or have ever had chloasma (a discolouration of the skin especially of the face or neck known as 'pregnancy patches'). In this case, avoid direct exposure to sunlight or ultraviolet light
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy [gestational herpes], a nerve disease causing sudden movements of the body [Sydenham's chorea])

BLOOD CLOTS
Using a combined hormonal contraceptive such as DROVELIS increases your risk of developing a blood clot compared with not using one. In rare cases, a blood clot can block blood vessels and cause serious problems.

Blood clots can develop
- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to DROVELIS is small.

HOW TO RECOGNISE A BLOOD CLOT
Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	**What are you possibly suffering from?**
• swelling of one leg or along a vein in the leg or foot especially when accompanied by: – pain or tenderness in the leg which may be felt only when standing or walking – increased warmth in the affected leg – change in colour of the skin on the leg e.g. turning	Deep vein thrombosis

pale, red or blue	
• sudden unexplained breathlessness or rapid breathing • sudden cough without an obvious cause, which may bring up blood • sharp chest pain which may increase with deep breathing • severe light headedness or dizziness • rapid or irregular heartbeat • severe pain in your stomach If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone • fullness, indigestion or choking feeling • upper body discomfort radiating to the back, jaw, throat, arm and stomach • sweating, nausea, vomiting or dizziness • extreme weakness, anxiety, or shortness of breath • rapid or irregular heartbeats	Heart attack
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body • sudden confusion, trouble speaking or understanding • sudden trouble seeing in one or both eyes • sudden trouble walking, dizziness, loss of balance or coordination • sudden, severe or prolonged headache with no known cause • loss of consciousness or fainting with or without seizure Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
• swelling and slight blue discolouration of an extremity	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung, it can cause a pulmonary embolism.

- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?
The risk of developing a blood clot in a vein is highest during the first year of taking combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same medicine or a different medicine) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop DROVELIS your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?
The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with DROVELIS is small.
- Out of 10 000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10 000 women who are using a combined hormonal contraceptive that contains low dose ethinylestradiol (< 50 µg ethinylestradiol) combined with levonorgestrel, norethisterone, or norgestimate about 5 – 7 will develop a blood clot in a year.
- It is not yet known how the risk of a blood clot with DROVELIS compares to the risk with a combined hormonal contraceptive that contains levonorgestrel.
- The risk of having a blood clot will vary according to your personal medical history (see 'Factors that increase your risk of a blood clot' below).

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10 000 women
Women using a combined hormonal contraceptive pill containing low-dose ethinylestradiol (< 50 microgram ethinylestradiol) combined with levonorgestrel, norethisterone or norgestimate	About 5 – 7 out of 10 000 women
Women using DROVELIS	Not yet known

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with DROVELIS is small but some conditions will increase the risk. Your risk is higher:
- if you are very overweight (body mass index or BMI over 30 kg/m^2)
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50 years). In this case you could have a hereditary blood clotting disorder
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of DROVELIS may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop DROVELIS ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years)

- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that DROVELIS needs to be stopped.

If any of the above conditions change while you are using DROVELIS, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY
What can happen if a blood clot forms in an artery?
Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to note that the risk of a heart attack or stroke from using DROVELIS is very small but can increase:
- with increasing age (beyond about 35 years)
- **if you smoke**. When using a combined hormonal contraceptive like DROVELIS, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 years your doctor may advise you to use a different type of contraceptive
- if you are overweight
- if you have high blood pressure
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50 years). In this case you could also have a higher risk of having a heart attack or stroke
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides)
- if you get migraines, especially migraines with aura
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using DROVELIS, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

Cancer
Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example, it may be that tumours are detected more in women on combination pills because they are examined by their doctor more often. After stopping the combination pill, the increased risk gradually reduces. It is important to check your breasts regularly and you should contact your doctor if you feel any lump. You should also tell your doctor if a close relative has, or ever had breast cancer (see section 2 ‘Warnings and precautions’).

In rare cases, benign (noncancerous) liver tumours, and in even fewer cases malignant (cancerous) liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain.

Cervical cancer is caused by an infection with the human papilloma virus (HPV). It has been reported to occur more often in women using the pill for more than 5 years. It is unknown if this finding is due to the use of hormonal contraceptives or to other factors, such as difference in sexual behaviour.

Psychiatric disorders
Some women using hormonal contraceptives including DROVELIS have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Bleeding between periods
Your period will normally start while you are taking the white placebo tablets in the DROVELIS pack.

During the first few months that you are taking DROVELIS, you may have unexpected bleeding (bleeding outside the placebo days). Mostly this bleeding is mild and usually not requiring any sanitary protection. If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

What you must do if no bleeding occurs during the placebo days
If you have taken all the pink active tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. Keep taking DROVELIS as usual.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant.

Children and adolescents
DROVELIS is only indicated after menarche (the first menstrual period). No data on efficacy and safety are available in adolescents below 16 years.

Other medicines and DROVELIS
Always tell your health care provider if you are taking any other medicines (This includes complementary or traditional medicines.).

Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take DROVELIS. They can tell you if you need to take additional contraceptive precautions (for example using condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Some medicines can have an influence on the blood levels of DROVELIS and can make it less effective in preventing pregnancy or can cause unexpected bleeding. These include medicines used for the treatment of:
- epilepsy (e.g. barbiturate, carbamazepine, phenytoin, primidone, felbamate, oxcarbazepine, topiramate)
- tuberculosis (e.g. rifampicin)
- HIV and hepatitis C virus (HCV) infections (e.g. so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as, ritonavir, nevirapine, efavirenz)
- fungal infections (e.g. griseofulvin)

- high blood pressure in the blood vessels in the lungs (e.g. bosentan)

The herbal product St. John's wort (*Hypericum perforatum*) may also stop DROVELIS from working properly. If you want to use herbal products containing St. John's wort while you are already using DROVELIS you should consult your doctor first.

If you are taking these medicines or herbal products that might make DROVELIS less effective, a barrier contraceptive method should also be used. The barrier method must be used during the whole time of the concomitant medicine therapy and for 28 days after its discontinuation If the concomitant medicine therapy runs beyond the end of the pink active tablets in the current pack, the white placebo tablets must be discarded and the next pack of DROVELIS should be started right away.

If long-term treatment with the above-mentioned medicines is necessary, you should use non-hormonal contraceptive methods. Ask your doctor or pharmacist for advice.

DROVELIS may influence the effect of other medicines, e.g.:
- ciclosporin (medicine used for the treatment of suppression of tissue rejection following transplant surgery)
- lamotrigine (medicine used for the treatment of epilepsy).

The HCV combination therapeutic regimen ombitasvir/paritaprevir/ritonavir and dasabuvir, with or without ribavirin, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. DROVELIS contains estetrol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using DROVELIS with this HCV combination therapeutic regimen. Your doctor will advise you.

Ask your doctor or pharmacist for advice before taking any medicine.

Laboratory tests
If you are having any blood or urinary test, tell your doctor that you are using DROVELIS as it may affect the results of some tests.

DROVELIS with food and drink
DROVELIS may be taken with or without food, if necessary with a small amount of water.

Pregnancy and breastfeeding
DROVELIS must not be taken by women who are pregnant or think they may be pregnant. If you become pregnant while taking DROVELIS, you should stop taking DROVELIS immediately and contact your doctor.

If you want to become pregnant, you can stop taking DROVELIS at any time (see section 3 'If you stop taking DROVELIS').

DROVELIS is not recommended during breastfeeding. If you wish to take the tablets while breastfeeding, you should contact your doctor.

Driving and using machines
DROVELIS can cause side effects, such as dizziness, visual impairment, blurred vision or fatigue. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how DROVELIS affects you.

DROVELIS contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DROVELIS.

The pink active tablet contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take DROVELIS

Do not share medicines prescribed for you with any other person.
Always take DROVELIS exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of DROVELIS is too strong or too weak, tell your doctor or pharmacist.

When and how to take the tablets
The DROVELIS blister contains 28 film-coated tablets: 24 pink active tablets with the active substances (number 1 – 24) and 4 white placebo tablets without active substances (number 25 – 28).

Each time you start a new blister of DROVELIS, take the number 1 pink active tablet (see 'Start').

Choose from the 7 weekday stickers, the one that begins with your starting day. For example, if you start on a Wednesday, use the day label sticker that starts with 'Wed'. Place it in the frame on the front of the blister card on the "→" symbol. Each day will line up with a row of pills. This allows you to check whether you took your daily tablet.

Take one tablet each day at about the same time, with some water if necessary.

Follow the direction of the arrows on the blister, so take the pink active tablets first and then the white placebo tablets.

Your period will start during the 4 days that you take the white placebo tablets (so-called withdrawal bleeding). Usually it will start 2 to 3 days after the last pink active tablet intake and may not have finished before the next blister is started.

Start taking your next blister immediately after the last white placebo tablet, even if your period has not finished. This means that you will always start a new blister on the same day of the week, and also that you have your period on roughly the same days each month.

Some users may not have their period every month during the intake of the white placebo tablets. If you have taken DROVELIS every day according to these instructions, it is unlikely that you are pregnant.

Starting your first pack of DROVELIS
If you have not used a contraceptive with hormones in the previous month
Begin with DROVELIS on the first day of the cycle (that is the first day of your period). If you start DROVELIS on the first day of your menstruation you are immediately protected against pregnancy.

You may also begin on day 2 – 5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

Changing from a combined hormonal contraceptive, or combined contraceptive vaginal ring or patch
You can start DROVELIS preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill finish (or after the last inactive tablet of your previous pill). When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.

Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing intra-uterine device [IUD])
You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 consecutive days of tablet-taking.

After a miscarriage
Follow the advice of your doctor.

After having a baby
You can start DROVELIS between 21 and 28 days after having a baby. If you start later than day 28, you must use a barrier method (for example, a condom) during the first 7 days of DROVELIS use. If, after having a baby, you have had sex before starting DROVELIS, you must first be sure that you are not pregnant or you must wait until your next period.

If you are breastfeeding and want to start DROVELIS (again) after having a baby
Read the section on “Breastfeeding”.

Ask your doctor or pharmacist what to do if you are not sure when to start.

If you take more DROVELIS than you should
There are no reports of serious harmful results of taking too many DROVELIS tablets. If you take several tablets at once, then you may feel sick or vomit or bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining DROVELIS with you so the doctor will know what you have taken.

If you forget to take DROVELIS
The last 4 white tablets of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of DROVELIS. Throw away the forgotten white placebo tablet.

If you miss a pink, active tablet (tablets 1 – 24 of your blister-strip), you must do the following:
- if you are less than 24 hours late taking a pink active tablet, the protection against pregnancy is not reduced. Take the tablet as soon as possible and then take the following tablets again at the usual time.
- if you are more than 24 hours late taking a pink active tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a pink active tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see also the diagram):

More than one tablet forgotten in this strip:

Contact your doctor.

One pink active tablet forgotten between days 1 – 7

Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use extra precautions, for example, a condom, for the next 7 days while taking the tablets correctly. If you have had sex in the week before forgetting the tablet you must realize that there is a risk of a pregnancy. In that case, contact your doctor.

One pink active tablet forgotten between days 8 – 17

Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

One pink active tablet forgotten between days 18 – 24

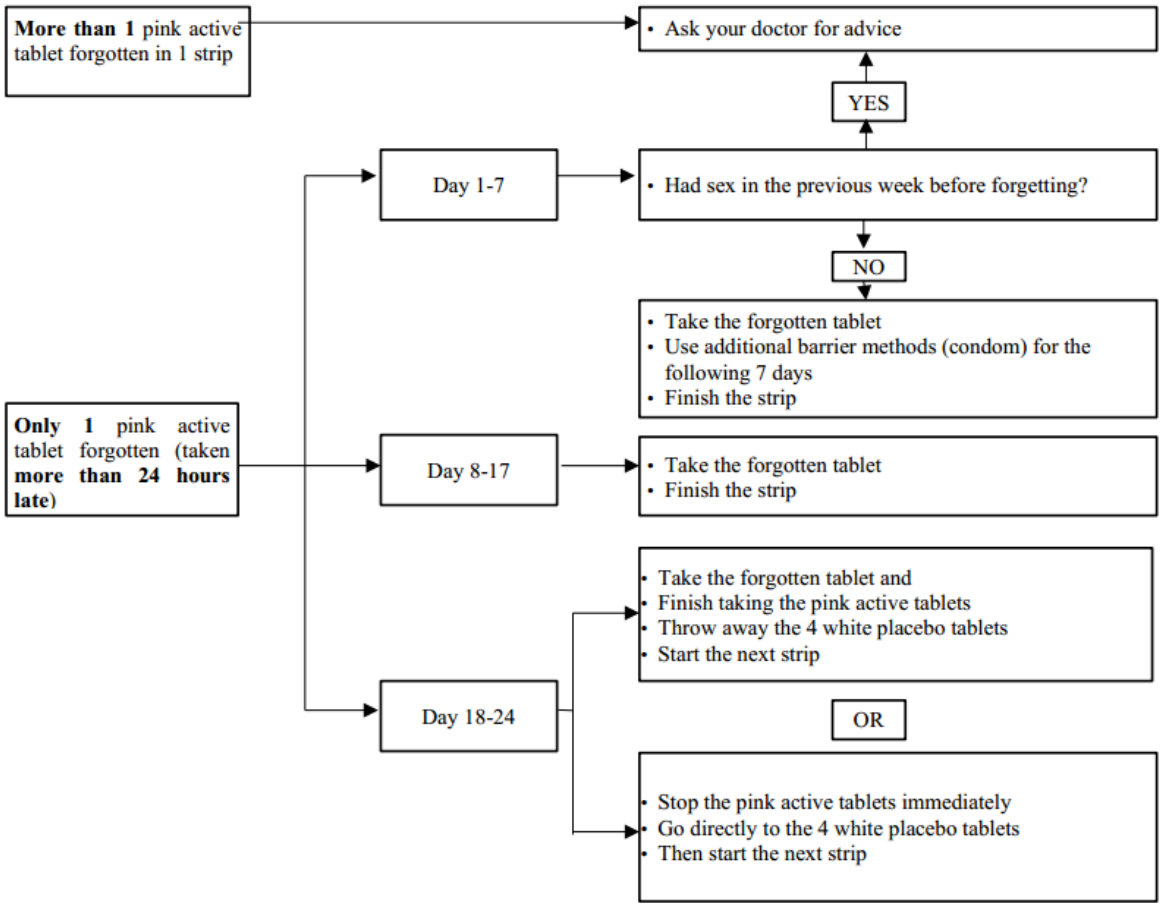
You can choose between two possibilities:

1. Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the white placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different).
   Most likely, you will have a period at the end of the second strip - while taking the white placebo tablets - but you may have light or menstruation-like bleeding during the second strip.
2. You can also stop the pink active tablets and go directly to the 4 white placebo tablets (before taking the white placebo tablets, record the day on which you forgot your tablet). If you want to start a new strip on the day you always start, take the white placebo tablets for less than 4 days.

If you follow one of these two recommendations, you will remain protected against pregnancy.

If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the placebo days, this may mean that you are pregnant. You must contact your doctor before you start the next strip.

Schedule if you are more than 24 hours late taking pink active tablets



More than one tablet forgotten in this strip
Follow the advice of your doctor.

If you vomit or have severe diarrhoea
If you vomit within 3-4 hours of taking a pink active tablet or have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, you must take another pink active tablet from a reserve strip as soon as possible. If possible take it within 24 hours of when you normally take your pill. If this is not possible or 24 hours have passed, you should follow the advice given under 'If you forget to take DROVELIS'.

Delaying your period: what you need to know
Even if it is not recommended, you can delay your period by not taking the white placebo tablets from the 4th row and going straight to a new strip of DROVELIS and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 4 white placebo tablets. Then start your next strip. You might ask your doctor for advice before deciding to delay your menstrual period.

If you want to change the starting day of your period
If you take the tablets according to the instructions, then your period will begin during the placebo days. If you have to change this day, reduce the number of placebo days – when you take the white placebo tablets – but never increase them (4 is the maximum). For example, if you start taking the white placebo tablets on Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new blister 3 days earlier than usual. You may not have any bleeding

during the shortened period of white placebo tablet intake. While using the next blister you may have some spotting (drops or flecks of blood) or breakthrough bleeding on pink active tablet-taking days.

If you are not sure what to do, speak with your doctor or pharmacist.

If you stop taking DROVELIS
You can stop taking DROVELIS at any time. If you do not want to become pregnant, first ask your doctor about other methods of birth control.

If you stop taking DROVELIS because you want to get pregnant, it is best to wait until you have had a natural period before trying to become pregnant. This will help you to calculate the expected delivery date more easily.

If you have any further questions on the use of DROVELIS, ask your doctor or pharmacist.

4. Possible side effects

DROVELIS can have side effects.

Not all side effects reported for DROVELIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DROVELIS, please consult your health care provider for advice.

An increased risk of blood clots in your veins (VTE) or blood clots in your arteries (ATE) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 ‘What you need to know before you take DROVELIS’.

If any of the following happens, stop taking DROVELIS and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DROVELIS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Side effects occurring frequently:
- mood disorder and disturbance, libido disorder
- headache
- abdominal pain, nausea
- acne
- breast pain, painful periods, vaginal bleeding (during or outside periods, heavy irregular bleeding)
- weight fluctuation

Side effects occurring less frequently:
- fungal infection, vaginal infection, urinary tract infection
- changes in appetite (appetite disorder)
- depression, emotional disorder, anxiety disorder, stress, problems sleeping
- migraine, dizziness, ‘pins and needles’, drowsiness
- hot flush
- abdominal (belly) swelling, vomiting, diarrhoea

- hair loss, excessive sweating (hyperhidrosis), dry skin, rash, skin swelling
- back pain
- swollen breasts, lumps in the breast, abnormal genital bleeding, pain with intercourse, fibrocystic breast disease (presence of one or more cysts in a breast), heavy periods, no periods, menstrual disorders, premenstrual syndrome, contractions of the uterus, uterine or vaginal bleeding including spotting, vaginal discharge, vulvovaginal disorder (dryness, pain, odour, discomfort)
- fatigue, swelling of parts of your body e.g. ankles (oedema), chest pain, feeling abnormal
- blood tests showing increased liver enzymes, changes in certain blood fats (lipids)
- breast inflammation
- benign breast mass
- fluid retention, increased potassium levels in the blood
- nervousness
- forgetfulness
- dry eye, visual blurring, visual impairment
- vertigo (a sense that you or your surroundings are spinning or moving)
- high or low blood pressure, inflammation of a vein with the formation of a blood clot (thrombophlebitis), varicose vein
- constipation, dry mouth, indigestion, lip swelling, flatulence, bowel inflammation, gastric reflux, abnormal bowel contractions
- allergic skin reactions, golden brown pigment patches (chloasma) and other pigmentation disorders, male pattern hair growth, excessive hair growth, skin conditions such as dermatitis and itchy dermatitis, dandruff and oily skin (seborrhoea) and other skin disorders
- muscle and joint cramps, pain and discomfort
- urinary tract pain, abnormal urine smell
- pregnancy that occurs outside the womb (ectopic pregnancy)
- ovarian cyst, increased spontaneous milk flow, pelvic pain, breast discolouration, bleeding during intercourse, endometrial disorders, nipple disorders, abnormal uterine bleeding
- malaise and feeling generally unwell, increase in body temperature, pain
- increase in blood pressure, changes in blood tests (abnormal kidney function test, increased blood potassium, increased blood glucose, decreased haemoglobin, decreased iron stores in blood, blood in urine)
- harmful blood clots in a vein for example
  - in a leg or foot (i.e. DVT)
  - in a lung (i.e. PE)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye

  The chance of having a blood clot may be higher if you have any other condition that increase this risk (see section 2 for more information on the conditions that increase the risk for blood clots and the symptoms of a blood clot).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of DROVELIS.

5. How to store DROVELIS

- Store at or below 25 °C.
- Keep the blister in the outer carton to protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DROVELIS contains

Each pink active tablet contains 3 mg drospirenone and estetrol monohydrate equivalent to 14,2 mg estetrol.

Each white placebo tablet does not contain active substances.

Pink active film-coated tablets:

Tablet core:

Lactose monohydrate, sodium starch glycolate, maize starch, povidone K30, magnesium stearate (E470b).

Tablet coating:

Hypromellose (E464), hydroxypropylcellulose (E463), talc (E553b), cottonseed oil, hydrogenated, titanium dioxide (E171), iron oxide red (E172).

White placebo film-coated tablets:

Tablet core:

Lactose monohydrate, maize starch, magnesium stearate (E470b).

Tablet coating:

Hypromellose (E464), hydroxypropylcellulose (E463), talc (E553b), cottonseed oil hydrogenated, titanium dioxide (E171).

What DROVELIS looks like and contents of the pack

The active film-coated tablets are pink, 6 mm diameter, round, biconvex with a drop-shaped logo embossed on one side.

The placebo film-coated tablets are white to off-white, 6 mm diameter, round, biconvex with a drop shaped logo embossed on one side.

DROVELIS is presented in transparent PVC/aluminium blister blisters of 28 film-coated tablets (24 pink active tablets and 4 white placebo tablets) packed in a carton. In addition to the blister(s), the DROVELIS box contains a small storage bag and 1, 3, 6, or 13 self-adhesive sticker(s) marked with days of the weeks. The numbers of self-adhesive stickers depend on the number of blisters.

Pack sizes: 28 (1 × 28), 84 (3 × 28), 168 (6 × 28) and 364 (13 × 28) film-coated tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in
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Registration number
56/18.8/0933

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: S4

DROVELIS 3 mg/14,2 mg filmbedekte tablette
drospirenoon / estetrol
Bevat suiker (elke pienk aktiewe tablet bevat 40 mg laktosemonohidraat en elke wit plasebo tablet bevat 68 mg laktosemonohidraat).

Lees hierdie voubiljet noukeurig voordat u DROVELIS begin gebruik
- Hou hierdie voubiljet. U mag dit weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- DROVELIS is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, al ervaar hulle dieselfde simptome indien u.

Wat in hierdie voubiljet is

1. Wat DROVELIS is en waarvoor dit gebruik word
DROVELIS is ’n voorbehoedpil wat gebruik word om swangerskap te voorkom.
- Die 24 pienk filmbedekte tablette is aktiewe tablette wat ’n klein hoeveelheid van twee verskillende vroulike hormone, naamlik estetrol en drospirenoon, bevat.
- Die 4 wit filmbedekte tablette is onaktiewe tablette wat geen hormone bevat nie en plasebo tablette genoem word.
- Voorbehoedpille wat twee verskillende hormone bevat, soos DROVELIS, word ‘kombinasie’ of ‘saamgestelde’ pille genoem. Hulle werk saam om ovulasie (vrystelling van ’n eiersel uit die eierstok) te voorkom en om die kans dat enige vrygestelde eier bevrug word en u swanger raak, te verminder.

2. Wat u moet weet voordat u DROVELIS gebruik
Algemene notas
Voordat u begin om DROVELIS te gebruik, moet u die inligting oor bloedklontvorming in afdeling 2 lees. Dit is veral belangrik om oor die simptome van ’n bloedklont te lees – sien afdeling 2 ‘Bloedklonte’.

Voordat u kan begin om DROVELIS te gebruik, sal u dokter vir u ’n paar vrae vra oor u persoonlike gesondheid-geskiedenis en dié van u nabye familie. Die dokter sal ook u bloeddruk meet en, afhangende van u persoonlike omstandighede, ook sekere toetse uitvoer.

Verskeie situasies word in hierdie voubiljet beskryf waarin u die gebruik van die pil moet staak, of waar die betroubaarheid van die pil kan afneem. In sulke situasie moet u nie seksuele omgang hê nie, of u moet bykomende nie-hormonale voorbehoeding gebruik, bv. gebruik van ’n kondoom of ander versperringsmetode. Moenie die ritme- of temperatuur-metodes gebruik nie. Hierdie metodes kan onbetroubaar wees, aangesien die pil die gewone veranderinge in temperatuur en servikale slym wat gedurende die menstruele siklus voorkom, verander.

Datum van goedkeuring: 30 Julie 2024

DROVELIS, soos ander hormonale voorbehoedmiddels, voorkom nie menslike immuniteitsgebrekvirus (MIV) (verworwe immuniteitsgebreksindroom (VIGS)) of ander seksueel-oordraagbare siektes nie.

Moenie DROVELIS gebruik nie
U moenie DROVELIS gebruik indien u aan enige van die toestande hieronder gelys ly nie. U moet u dokter inlig indien u enige van die onderstaande toestande het. U dokter sal met u bespreek watter ander vorme van geboortebeperking meer van toepassing sal wees.

- indien u hipersensitief (allergies) is vir estetrol of drospirenoon, of enige van die ander bestanddele van DROVELIS (gelys in afdeling 6).
- indien u 'n bloedklont in 'n bloedvat in u bene (diep veneuse trombose, DVT), u longe (pulmonale embolus, PE) of ander organe het (of ooit gehad het)
- indien u bewus is dat u 'n afwyking het wat u bloedklontvorming beïnvloed - byvoorbeeld proteïen C-tekort, proteïen S-tekort, antitrombien-III tekort, faktor V Leiden of antifosfolipied-teenliggaampies
- indien u 'n operasie moet ondergaan of indien u vir 'n lang tyd nie op u voete gaan wees nie (sien afdeling 'Bloedklonte')
- indien u ooit 'n hartaanval of beroerte gehad het
- indien u angina pectoris ('n toestand wat erge borspyn veroorsaak en die eerste tekens van 'n hartaanval kan wees) of tydelike iskemiese aanval (TIA – tydelike beroerte simptome) het (of ooit gehad het)
- indien u enige van die volgende siektes het, wat die risiko van 'n bloedklont in die are verhoog:
  - ernstige diabetes met bloedvatskade
  - baie hoë bloeddruk
  - 'n baie hoë vlak van vet in die bloed (cholesterol of trigliseriede)
  - 'n toestand bekend indien hiperhomosisteïnemie
- indien u 'n tipe migraine naamlik 'migraine met aura' het (of ooit gehad het)
- indien u 'n gewas in die lewer (kwaadaardig of nie-kwaadaardig) het (of ooit gehad het)
- indien u 'n lewersiekte het (of ooit gehad het) en u lewerfunksie is steeds nie normaal nie
- indien u niere nie goed werk nie (nierversaking)
- indien u borskanker het (of ooit gehad het), of vermoed dat u borskanker of kanker van die geslagsorgane het
- indien u enige onverklaarbare bloeding vanuit die vagina het

Indien enige van hierdie toestande vir die eerste keer opduik tydens gebruik van DROVELIS, staak gebruik onmiddellik en lig u dokter in. Gebruik intussen 'n nie-hormonale voorbehoedingsmetode. Sien ook 'Algemene notas' in afdeling 2 hierbo.

Waarskuwings en voorsorgmaatreëls
Raadpleeg u dokter of apteker voordat u DROVELIS gebruik.

Wanneer moet u dokter gekontak word?

Kry dringend mediese sorg

- indien u moontlike tekens van 'n bloedklont opmerk wat kan beteken dat u 'n bloedklont in die been (d.i. diep veneuse trombose), 'n bloedklont in die long (d.i. pulmonale embolisme), 'n hartaanval of beroerte het (sien 'Bloedklonte' afdeling hieronder).

Vir 'n beskrywing van die simptome van hierdie ernstige newe-effekte, gaan lees asseblief 'Hoe om 'n bloedklont uit te ken'.

Lig u dokter in indien enige van die volgende toestande op u van toepassing is
U moet u dokter inlig indien dié toestand ontwikkel of vererger tydens gebruik van DROVELIS:

- indien 'n nabye familielid borskanker het, of ooit gehad het

- indien u oorerflike angio-edeem het. Medisynes wat estrogene bevat kan simptome van angio-edeem veroorsaak of vererger. Besoek u dokter onmiddellik indien u simptome van angio-edeem ervaar, soos geswelde gesig, tong en/of keel en/of moeite om te sluk of galbulte, saam met moeite om asem te haal.
- indien u lewersiekte of galblaassiekte het
- indien u diabetes het
- indien u depressie het
- indien u epilepsie het (sien afdeling 2 'Ander medisyne en DROVELIS')
- indien u Crohn se siekte of ulseratiewe kolitis (chroniese inflammatoriese dermsiekte) het
- indien u sistemiese lupus eritematose (SLE – 'n siekte wat u natuurlike verdedigingstelsel beïnvloed) het
- indien u hemolitiese uremiese sindroom (HUS – 'n versteuring van bloedklontvorming wat nierversaking veroorsaak) het
- indien u sekelsel-anemie ('n oorerflike siekte van die rooi bloedselle)
- indien u verhoogde vlakke van vet in u bloed (hipertrigliseriedemie) of 'n positiewe geskiedenis van hierdie toestand in u familie het. Hipertrigliseriedemie is met 'n verhoogde risiko vir die ontwikkeling van pankreatitis (inflammasie van die pankreas) verbind
- indien u 'n operasie moet ondergaan of indien u vir 'n lang tydperk nie op u voete gaan wees nie (sien afdeling 2 'Bloedklonte')
- indien u onlangs 'n bevalling gehad het, het u 'n verhoogde risiko vir bloedklontvorming. U moet u dokter vra hoe gou na u bevalling gehad het, u kan begin om DROVELIS gebruik
- indien u inflammasie in die are onder die vel (oppervlakkige tromboflebitis) het
- indien u spatare het
- indien u chloasma ('n verkleuring van die vel, veral van die gesig en nek, bekend as 'swangerskapkolle') het, of ooit gehad het. In hierdie geval moet u direkte blootstelling aan sonlig of ultravioletstrale vermy
- indien u 'n siekte het wat vir die eerste keer tydens swangerskap of vroeëre gebruik van geslagshormone verskyn (byvoorbeeld, gehoorverlies, 'n bloedsiekte wat porfirie genoem word, veluitslag met blase tydens swangerskap [swangerskap-herpes], 'n senuweesiekte wat skielike beweging van die liggaam veroorsaak [Sydenham se chorea])

BLOEDKLONTE

Die gebruik van 'n saamgestelde hormonale voorbehoedmiddel soos DROVELIS verhoog u risiko om 'n bloedklont te ontwikkel, in vergelyking met die nie-gebruik daarvan. In skaars gevalle kan 'n bloedklont are blok en ernstige probleme veroorsaak.

Bloedklonte kan ontwikkel

- in are (waarna verwys word as 'veneuse trombose', 'veneuse trombo-embolus' of VTE)
- in die slagare (waarna verwys word as 'slagaar-trombose', slagaar-trombo-embolus' of STE).

Herstel van bloedklonte is nie altyd volledig nie. In skaars gevalle kan daar ernstige blywende gevolge voorkom, of in baie skaars gevalle kan dit dodelik wees.

Dit is belangrik om te onthou dat die algehele risiko van 'n skadelike bloedklont as gevolg van DROVELIS klein is.

HOE OM 'N BLOEDKLONT UIT TE KEN

Kry dringende mediese aandag indien u enige van die volgende tekens of simptome opmerk.

PASIËNT INLIGTINGSBILJET

Ervaar u enige van hierdie tekens?	**Waaraan ly u moontlik?**
• swelling van een been of teen 'n aar in die been of voet, veral wanneer dit met die volgende gepaard gaan: – pyn of teerheid in die been wat net gevoel kan word indien u staan of loop – verhoogde temperatuur in die aangetaste been – verandering van kleur van die vel op die been, bv. dit word bleek, rooi of blou	Diep veneuse trombose
• skielike onverklaarbare asemnood of vinnige asemhaling • skielike hoes sonder 'n merkbare oorsaak, wat met uithoes van bloed gepaard kan gaan • skerp borspyn wat met diep asemhaling kan vererger • erge lighoofdigheid of duiseligheid • vinnige of ongereelde hartklop • erge maagpyn Indien u onseker is, raadpleeg 'n dokter, aangesien hierdie simptome soos hoes of kortasem verwar kan word met 'n minder ernstige toestand soos 'n lugweginfeksie (bv. 'n "verkoue").	Pulmonale embolus
Simptome wat meestal in een oog voorkom: • onmiddellike verlies van sig of pynlose versteuring van visie, wat kan vererger tot verlies van sig	Retinale veneuse trombose (bloedklont in die oog)
• borspyn, ongemak, druk, swaar gevoel • sensasie van drukking of volheid in die bors, arm of onder die borsbeen • volheid, slegte spysvertering of gevoel van verstikking • ongemak in die bolyf wat na die rug, kakebeen, keel, arm of maag uitsprei • sweet, naarheid, braking of duiseligheid • uitermatige swakheid, angs, of kortasem • vinnige of ongereelde hartklop	Hartaanval

• skielike swakheid of gevoelloosheid van die gesig, arm of been, veral aan een kant van die liggaam • skielike verwarring, moeite om te praat of te verstaan • skielike probleme om te sien met een of albei oë • skielike probleme om te loop, duiseligheid, verlies van balans of koördinasie • skielike, erge of voortdurende hoofpyn met geen merkbare oorsaak • verlies van bewussyn of foute met of sonder stuipe Soms kan die simptome van beroerte kortstondig wees met bykans onmiddellike en volkome herstel, maar u moet steeds dringend mediese hulp soek, aangesien u 'n risiko het om nog 'n beroerte te kry.	Beroerte
• swelling en effense blou verkleuring van 'n ledemaat	Bloedklonte wat ander are blokkeer

BLOEDKLONTE IN 'N AAR

Wat kan gebeur indien 'n bloedklont in 'n aar vorm?

- Die gebruik van saamgestelde hormonale voorbehoedmiddels is met 'n verhoogde risiko van bloedklonte in die aar (veneuse trombose) verbind. Nieteenstaande is hierdie newe-effekte skaars. Dit kom meestal in die eerste jaar van gebruik van saamgestelde hormonale voorbehoedmiddels voor.
- Indien 'n bloedklont in 'n aar in die been of voet vorm, kan dit diep veneuse trombose (DVT) veroorsaak.
- Indien 'n bloedklont van die been tot in die long beweeg en daar vassit, kan dit 'n pulmonale embolus veroorsaak.
- 'n Bloedklont kan baie selde in 'n ander orgaan vorm, soos die oog (retinale veneuse trombose).

Wanneer is die risiko om 'n bloedklont in 'n aar te ontwikkel die hoogste?

Die risiko vir 'n bloedklont om in 'n aar te vorm is die hoogste gedurende die eerste jaar van die eerste gebruik van saamgestelde hormonale voorbehoedmiddels. Die risiko kan ook verhoog word indien u weer begin om 'n saamgestelde hormonale voorbehoedmiddel (dieselfde of 'n ander medisyne), na 'n onderbreking van 4 weke of meer, te gebruik.

Na die eerste jaar word die risiko kleiner, maar is altyd effens hoër as wanneer u nie 'n saamgestelde hormonale voorbehoedmiddel gebruik het nie.

Wanneer u gebruik van DROVELIS staak, keer u risiko vir 'n bloedklont binne 'n paar weke terug na normaal.

Wat is die risiko om 'n bloedklont te ontwikkel?

Die risiko hang van u natuurlike risiko van VTE en die tipe saamgestelde hormonale voorbehoedmiddel wat u gebruik, af.

Die algehele risiko van 'n bloedklont in die been of long (DVT of PE) met DROVELIS is klein.

- Uit 10 000 vroue wie nie saamgestelde hormonale voorbehoedmiddels gebruik en nie swanger is nie, sal ongeveer 2 vroue binne 'n jaar 'n bloedklont ontwikkel.
- Uit 10 000 wie 'n saamgestelde hormonale voorbehoedmiddel wat 'n lae dosis

etinielestradiool (< 50 µg etinielestradiool) saam met levonorgestrel, noretisteroon of norgestimaat gebruik, sal ongeveer 5 – 7 vroue 'n bloedklont binne 'n jaar ontwikkel.
- Dit is nog onbekend hoe die risiko van 'n bloedklont met DROVELIS vergelyk met die risiko van 'n saamgestelde hormonale voorbehoedmiddel wat levonorgestrel bevat nie.
- Die risiko om 'n bloedklont te ontwikkel sal verskil volgens u persoonlike mediese geskiedenis (sien 'Faktore wat u risiko van 'n bloedklont verhoog' hieronder).

	Risiko om 'n bloedklont binne 'n jaar te ontwikkel
Vroue wie **nie** 'n saamgestelde hormonale pil/plakker/ring **gebruik** en nie swanger is nie	Ongeveer 2 uit 10 000 vroue
Vroue wie 'n saamgestelde hormonale voorbehoedpil gebruik wat 'n lae dosis etinielestradiool bevat (< 50 mikrogram etinielestradiool) saam met levonorgestrel, noretisteroon of norgestimaat	Ongeveer 5 – 7 uit 10 000 vroue
Vroue wie DROVELIS gebruik	Nog nie bekend nie

Faktore wat u risiko vir 'n bloedklont in 'n aar verhoog
Die risiko van 'n bloedklont met DROVELIS is klein maar sommige toestande sal die risiko verhoog. U risiko is hoër:
- indien u baie oorgewig is (liggaamsmassa indeks of LMI oor 30 kg/m^2)
- indien een van u onmiddellike familie 'n bloedklont in die been, long of ander orgaan op 'n jong ouderdom (bv. onder die ouderdom van 50 jaar) gehad het. In hierdie geval kan u 'n oordraagbare bloedstollings-versteuring hê
- indien u 'n operasie moet ondergaan, of u is lank nie op u voete nie as gevolg van 'n besering of siekte, of u been is in gips. Die gebruik van DROVELIS mag verskeie weke voor sjirurgie of terwyl u minder beweeglik is, gestaak moet word. Indien u gebruik van DROVELIS moet staak, vra u dokter wanneer u dit weer kan begin gebruik.
- indien u ouer word (veral bo ongeveer 35 jare)
- indien u minder as 'n paar weke gelede gekraam het.

Hoe meer toestande u het, hoe hoër die risiko om 'n bloedklont te ontwikkel.

Lugvervoer (> 4 ure) kan u risiko vir 'n bloedklont tydelik verhoog, veral indien u sommige van die ander genoemde faktore het.

Dit is belangrik om u dokter in te lig indien enige van hierdie toestande op u van toepassing is, al is u onseker. U dokter mag besluit dat die gebruik van DROVELIS gestaak moet word.

Indien enige van die bogenoemde toestande verander terwyl u DROVELIS gebruik, byvoorbeeld 'n nabye familielid ervaar 'n trombose vir geen merkbare rede nie; of u tel baie gewig op, lig u dokter in.

BLOEDKLONTE IN 'N SLAGAAR
Wat kan gebeur indien 'n bloedklont in 'n slagaar vorm?
'n Bloedklont in 'n slagaar kan, net soos 'n bloedklont in 'n aar, ernstige probleme veroorsaak. Dit kan byvoorbeeld 'n hartaanval of beroerte veroorsaak.

Faktore wat u risiko vir 'n bloedklont in 'n slagaar verhoog
Dit is belangrik om op te let dat die risiko van 'n hartaanval of beroerte met gebruik van DROVELIS baie klein is maar kan verhoog:

- met gevorderde ouderdom (ouer as ongeveer 35 jaar)
- **indien u rook**. U word aangeraai om op te hou rook indien u ’n saamgestelde hormonale voorbehoedmiddel soos DROVELIS gebruik. Indien u nie kan ophou rook nie en u is ouer as 35 jaar kan u dokter aanbeveel dat u ’n ander voorbehoedmiddel gebruik
- indien u oorgewig is
- indien u hoë bloeddruk het
- indien ’n lid van u onmiddellike familie ’n hartaanval of beroerte op ’n jong ouderdom (jonger as 50 jaar oud) gehad het. In hierdie geval kan u ook ’n hoër risiko vir ’n hartaanval of beroerte hê
- indien u, of iemand in u onmiddellike familie, ’n hoë vlak van vet in die bloed het (cholesterol of trigliseriede) het
- indien u migraine, veral migraine met aura, kry
- indien u ’n probleem met u hart het (klepversteuring, versteuring van die ritme wat atriale fibrillasie genoem word)
- indien u diabetes het.

Indien u meer as een van hierdie toestande het of indien enige van hulle besonder erg is, kan die risiko om ’n bloedklont te onwikkel verhoog.

Lig u dokter in indien enige van die bogenoemde toestande verander terwyl u DROVELIS gebruik, byvoorbeeld indien u begin rook, ’n nabye familielid ’n trombose vir geen merkbare rede ervaar; of u tel baie gewig op.

Kanker
Borskanker is effens meer gereeld opgemerk by vroue wat saamgestelde pille gebruik, maar dit is nie bekend of dit deur die behandeling veroorsaak word nie. Dit kan byvoorbeeld wees dat gewasse meer opgemerk word by vroue op saamgestelde pille, omdat hulle meer dikwels deur hulle dokters ondersoek word. Na staking van die saamgestelde pil verminder die risiko geleidelik. Dit is belangrik om u borste gereeld te ondersoek en u moet u dokter kontak indien u enige knop voel. U moet ook u dokter inlig indien ’n nabye familielid borskanker het of ooit gehad het (sien afdeling 2 ‘Waarskuwings en voorsorgmaatreëls’).

In seldsame gevalle is nie-kwaadaardige (nie-kankeragtige) lewergewasse by pilgebruikers aangemeld, en in nog minder gevalle, kwaadaardige (kankeragtige) lewergewasse. Kontak u dokter indien u buitengewone erge abdominale pyn ervaar.

Servikskanker word veroorsaak word deur ’n infeksie met die menslike papilloom virus (MPV). Dit word meer dikwels aangemeld by vroue wat die pil vir meer indien 5 jaar gebruik. Dit is onbekend of hierdie gevolgtrekking aan die gebruik van hormonale voorbehoedmiddels toegeskryf kan word, of aan ander faktore, soos ’n verandering in seksuele gedrag.

Psigiatriese versteurings
Sommige vroue wat hormonale voorbehoedmiddels, insluitende DROVELIS gebruik, het depressie of depressiewe buie aangemeld. Depressie kan baie ernstig wees en kan somtyds tot selfdoodgedagtes lei. Indien u gemoedsveranderinge en depressiewe simptome ervaar, kontak u dokter so gou as moontlik vir verdere mediese advies.

Bloeding tussen menstruasie
U menstruasie sal gewoonlik begin terwyl u die wit plasebo tablette in die DROVELIS-pak gebruik.

U kan onverwagte bloeding (bloeding wat nie gedurende die plasebo dae voorkom nie) tydens die eerste paar maande van gebruik van DROVELIS ervaar. Hierdie bloeding is meestal lig en het gewoonlik nie sanitêre beskerming nodig nie. Indien hierdie bloeding vir langer as ’n paar maande aanhou, of indien dit na ’n paar maande begin, moet u dokter vasstel wat

verkeerd is.

Wat u moet doen indien geen bloeding tydens plasebo dae voorkom nie
Indien u al die pienk tablette korrek gebruik het, nie braking of erge diarree gehad het nie en u nie ander medikasie te gebruik nie, is dit hoogs onwaarskynlik dat u swanger is. Hou aan om DROVELIS soos gewoonlik te gebruik.

Indien die verwagte bloeding twee keer in ’n ry nie gebeur nie, kan u swanger wees. Kontak u dokter onmiddellik. Begin slegs met die volgende stulpstrokie indien u seker is u is nie swanger nie.

Kinders en adolessente
DROVELIS word slegs aanbeveel na eerste maandstonde (die eerste menstruasie). Geen data oor die doeltreffendheid en veiligheid is beskikbaar vir adolessente onder 16 jaar oud nie.

Ander medisyne en DROVELIS
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne gebruik. (Dit sluit alle komplementêre en tradisionele medisynes in.).

Lig ook enige ander dokter of tandarts in, wat ander medisyne voorskryf (of die apteker), dat u DROVELIS gebruik. Hulle sal u kan sê of dit nodig is om bykomende voorbehoedingsmaatreëls (bv. gebruik van kondome) te gebruik, en indien wel, vir hoe lank, of indien die gebruik van ’n ander medisyne verander moet word.

Sommige medisynes kan ’n invloed op die bloedvlakke van DROVELIS hê en dit minder doeltreffend maak om swangerskap te voorkom, of kan onverwagte bloeding veroorsaak. Dit sluit medisyne vir die behandeling van die volgende in:
- epilepsie (e.g. barbiturate, karbamasepien, fenitoïen, primidoon, felbamaat, okskarbasepien, topiramaat)
- tuberkulose (bv. rifampisien)
- MIV en hepatitis C virus (HCV)-infeksies (bv. sogenaamde protease inhibeerders en nie-nukleosied omgekeerde transkriptase inhibeerders soos ritonavir, nevirapien, efavirens)
- swaminfeksies (bv. griseofulvien)
- hoë bloeddruk in die bloedvate in die longe (bv. bosentan)

Die kruieproduk “St. John’s wort” (*Hypericum perforatum*) kan ook die effektiewe werking van DROVELIS stop. U moet eers u dokter raadpleeg indien u kruieprodukte wil gebruik wat “St. John’s wort” bevat terwyl u alreeds DROVELIS.

Indien u hierdie medisyne of kruieprodukte gebruik, wat DROVELIS minder doeltreffend kan maak, moet ’n versperring-voorbehoedingsmetode ook gebruik word. Die versperringsmetode moet die hele tyd tydens gebruik van die gelyktydige medisyne terapie en vir 28 dae na staking van die terapie gebruik word. Indien die gelyktydige medisyne terapie vir langer as die einde van die pienk aktiewe tablette in die huidige pak duur, moet die wit plasebo tablette weggegooi word en die volgende pak DROVELIS moet onmiddellik begin word.

Indien langtermyn behandeling met die bogenoemde medisyne nodig is, moet u ’n nie-hormonale voorbehoedingsmetode gebruik. Vra u dokter of apteker vir advies.

DROVELIS kan die doeltreffendheid van ander medisynes beïnvloed, bv.:
- siklosporien (medisyne wat vir die behandeling of onderdrukking van weefsel-verwerping na oorplanting-sjirurgie gebruik word)
- lamotrigien (medisyne wat vir die behandeling van epilepsie gebruik word).

By vroue wat KHKs wat etinielestradiool bevat gebruik, kan die HCV kombinasie terapeutiese regimen ombitasvir/paritaprevir/ritonavir en dasabuvir, met of sonder ribavirin, glecaprevir/pibrentasvir of sofosbuvir/velpatasvir/voksilaprevir, verhoging in lewerfunksie bloedtoets-uitslae (verhoging in ALT-lewerensiem) veroorsaak. DROVELIS bevat estetrol in plaas van etinielestradiool. Dit is nie bekend of 'n verhoging in ALT-lewerensiem tydens gebruik van DROVELIS saam met hierdie HCV kombinasie terapeutiese regimen kan voorkom nie. U dokter sal u inlig.

Vra u dokter of apteker vir advies voordat u enige medisyne gebruik.

Laboratoriumtoetse
Lig u dokter in dat u DROVELIS gebruik indien u bloed- of urientoetse laat doen, aangesien die gebruik van DROVELIS die uitslae van sommige toetse kan beïnvloed.

DROVELIS met kos en drank
DROVELIS kan met of sonder kos geneem word, indien nodig met 'n klein hoeveelheid water.

Swangerskap en borsvoeding
DROVELIS moenie deur vroue wat swanger is, of wat dink hulle kan swanger wees, gebruik word nie. Indien u swanger raak terwyl u DROVELIS gebruik moet u die gebruik van DROVELIS onmiddellik staak en u dokter kontak.

Indien u swanger wil raak kan u die gebruik van DROVELIS enige tyd staak (sien afdeling 3 'Indien u die gebruik van DROVELIS staak').

DROVELIS word nie aanbeveel tydens borsvoeding nie. U moet u dokter kontak indien u verkies om die tablette tydens borsvoeding te gebruik.

Bestuur en hantering van masjinerie
DROVELIS kan newe-effekte veroorsaak, soos duiseligheid, verswakte sig, versteurde visie of uitputting. Moenie 'n voertuig bestuur of masjinerie hanteer, of enigiets anders doen wat u aandag nodig het totdat u weet hoe DROVELIS u beïnvloed nie.

DROVELIS bevat laktose en natrium
Kontak u dokter indien hy u ingelig het dat u 'n onverdraagsaamheid vir sommige suikers het voordat u begin om DROVELIS te gebruik.

Die pienk aktiewe tablette bevat minder indien 1 mmol natrium (23 mg) per tablet, dit is so te sê essensieel 'natrium-vry'.

3. Hoe om DROVELIS te gebruik

Moenie medisynes wat aan u voorgeskryf is met enige ander persoon deel nie.
Gebruik DROVELIS altyd presies soos dit in hierdie voubiljet of deur u dokter of apteker voorgeskryf is. Raadpleeg u dokter of apteker indien u onseker is.

Vertel u dokter of apteker indien u die indruk kry dat die uitwerking van of DROVELIS te sterk of te swak is.

Wanneer en hoe om die tablette te gebruik
Die DROVELIS stulpstrook bevat 28 film-bedekte tablette: 24 pienk aktiewe tablette met die aktiewe bestanddele (nommer 1 – 24) en 4 wit plasebo tablette sonder aktiewe bestanddele (nommer 25 – 28).

Neem die nommer 1 pienk tablet elke keer wanneer u 'n nuwe stulpstrook van DROVELIS begin gebruik (sien 'Begin').

Kies vanuit die 7 weeksdag-plakkers die plakker wat ooreenstem met u aanvangsdag. By voorbeeld, indien u op ’n Woensdag begin, gebruik die plakker wat met ‘Wo’ begin. Plaas dit in die raampie op die voorkant van die stulpstrook-kaart op die “→” simbool. Elke dag sal in lyn wees met ’n ry pille. Dit stel u in staat om te verseker dat u daaglikse tablet geneem is.

Neem een tablet elke dag ongeveer dieselfde tyd, met ’n bietjie water, indien nodig.

Volg die rigting van die pyltjies op die stulpstrook, neem dus eers die pienk aktiewe tablette en dan die wit plasebo tablette.

U sal begin menstrueer tydens die 4 dae wat u die wit plasebo tablette neem (sogenaamde onttrekking-bloeding). Dit sal gewoonlik begin 2 tot 3 dae ná die inname van die laaste pienk tablet, en kan moontlike nog nie opgeklaar wees voordat die volgende stulpstrook begin word nie.

Begin gebruik van u volgende stulpstrook onmiddellik na die laaste wit plasebo tablet selfs al is u menstruasie nog nie klaar nie. Dit beteken dat u altyd ’n nuwe stulpstrook op dieselfde dag van die week sal begin, en ook dat u op min of meer dieselfde dag van elke maand sal begin menstrueer.

Sommige gebruikers mag nie elke maand tydens die inname van die wit plasebo tablette menstrueer nie. Indien u DROVELIS elke dag volgens hierdie instruksies gebruik het, is dit onwaarskynlik dat u swanger is.

Begin van u eerste pak DROVELIS
Indien u nie ’n voorbehoedmiddel met hormone in die vorige maand gebruik het nie
Begin met DROVELIS op die eerste dag van die siklus (dit is die eerste dag van u menstruasie. Indien u DROVELIS op die eerste dag van u menstruasie begin gebruik is u onmiddellik teen swangerskap beskerm.

U kan ook op dag 2 – 5 van die siklus begin, maar dan moet u bykomende voorsorgmaatreëls (byvoorbeeld om ’n kondoom te gebruik) vir die eerste 7 dae van gebruik van die tablette tref.

Oorskakeling van ’n saamgestelde hormonale voorbehoedmiddel, of saamgestelde voorbehoedende vaginale ring of plakker
U kan met DROVELIS begin, verkieslik op die dag na die laaste aktiewe tablet (die laaste tablet wat aktiewe bestanddele bevat) van u vorige pil, maar op die laatste op die dag na die tablet-vrye dae van u vorige pil klaar is (of na die laaste onaktiewe tablet van u vorige pil). Volg die raad van u dokter wanneer u vanaf ’n saamgestelde voorbehoedende vaginale ring of plakker verander.

Oorskakeling van ’n progestogeen-alleen-metode (progestogeen-alleen pil, inspuiting, inplanting of ’n progestogeen-vrystellende intra-uteriene toestel [IUT])
U mag enige dag van die progestogeen-alleen pil verander (vir ’n inplanting of ’n IUT op die dag van die verwydering daarvan, vir ’n inspuiting, wanneer dit tyd is vir die volgende inspuiting) maar in al hierdie gevalle moet u bykomende voorsorgmaatreëls (byvoorbeeld die gebruik van ’n kondoom) tref vir die eerste 7 opeenvolgende dae van tablet-inname.

Na ’n miskraam
Volg die advies van u dokter

Nadat u ’n baba gehad het
U kan DROVELIS tussen 21 en 28 dae na u ’n baba gehad het begin gebruik. Indien u later as dag 28 met gebruik begin, moet u ’n versperringsmetode (byvoorbeeld gebruik van ’n

kondoom) tydens die eerste 7 dae van gebruik van DROVELIS toepas. Indien u seks gehad het na die geboorte van u baba, voordat u DROVELIS begin gebruik, moet u eers seker maak dat u nie swanger is nie, of u moet tot u volgende menstruasie wag.

Indien u borsvoed en u wil (weer) begin om DROVELIS te gebruik na geboorte van 'n baba
Lees die afdeling oor "Borsvoeding".

Vra u dokter of apteker wat om te doen indien u nie seker wanneer om te begin nie.

Indien u meer DROVELIS gebruik as wat u moes
Daar is geen aanmeldings van ernstige nadelige gevolge vir oorgebruik van DROVELIS tablette nie. Indien u verskeie tablette gelyktydig neem, kan u naar voel of braak of bloeding vanuit die vagina hê. Selfs meisies wat nog nie begin menstrueer het nie maar per ongeluk hierdie medisyne neem, kan hierdie bloeding ervaar.

Raadpleeg u dokter of apteker in die geval van oordosering. Kontak die naaste hospitaal of gifhulpsentrum indien nie een van hulle beskikbaar is nie.

Neem hierdie voubiljet en die oorblywende DROVELIS tablette saam sodat die dokter kan weet hoeveel u geneem het.

Indien u vergeet om DROVELIS te gebruik
Die laaste 4 wit tablette van die stulpstrook is die plasebo tablette. Indien u vergeet om een van hierdie tablette te neem het dit geen invloed op die betroubaarheid van DROVELIS nie. Gooi die vergete wit plasebo tablet weg.

Indien u 'n pienk aktiewe tablet mis (tablette 1 – 24 van u stulpstrook), moet u die volgende doen:
- indien u minder as 24 ure laat is om die pienk aktiewe tablet te neem, is die beskerming teen swangerskap nie verminder nie. Neem die tablet so gou as moontlik en neem die volgende tablette weer op die gewone tyd.
- Indien u meer as 24 ure laat is om die pienk aktiewe tablet te neem, kan die beskerming teen swangerskap verminder wees. Hoe meer tablette u vergeet het, hoe groter is die risiko dat u swanger kan raak.

Die risiko van onvolledige beskerming teen swangerskap is die grootste as u vergeet om 'n pienk aktiewe tablet aan die begin of einde van die stulpstrook te neem. U moet daarom die by die volgende reëls hou (sien ook die diagram):
Meer as een tablet vergeet in hierdie stulpstrook:
Kontak u dokter.

Een pienk aktiewe tablet vergeet tussen dae 1 – 7
Neem die vergete tablet so gou as moontlik, selfs al beteken dit dat u twee tablette gelyktydig moet neem. Gaan voort om die tablette op die gewone tyd te neem en tref bykomende voorsorg, byvoorbeeld die gebruik van 'n kondoom, vir die volgende 7 dae terwyl u die tablette korrek gebruik. Indien u seks gehad het in die voorafgaande week, voor u die tablette vergeet het, moet u besef dat daar 'n risiko is dat u swanger kan wees. Kontak u dokter in daardie geval.

Een pienk aktiewe tablet vergeet tussen dae 8 – 17
Neem die vergete tablet so gou as moontlik, selfs al beteken dit dat u twee tablette gelyktydig moet neem. Gaan voort om die tablette op die gewone tyd te neem. Die beskerming teen swangerskap is nie verminder nie en u hoef nie bykomende voorsorg te tref nie.

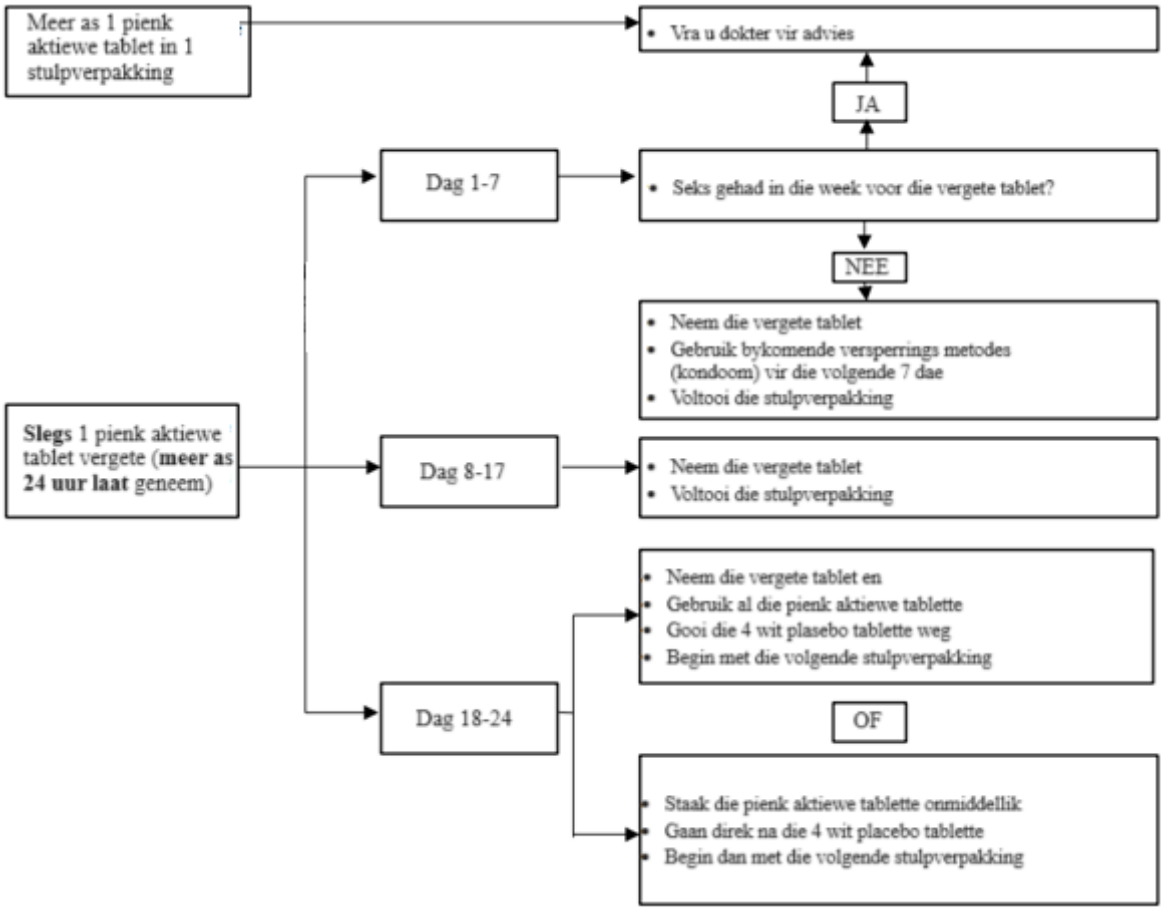
Een pienk aktiewe tablet vergeet tussen dae 18 – 24
U kan kies tussen twee moontlikhede:

1. Neem die vergete tablet so gou as moontlik, selfs al beteken dit dat u twee tablette gelyktydig moet neem. Gaan voort om die tablette op die gewone te neem. In plaas daarvan om die wit plasebo tablette op hierdie stulpstrook te neem, gooi hulle weg en begin met die volgende stulpstrook (die begin dag sal verskillend wees).
   U sal moontlik aan die einde van die tweede stulpstrook menstrueer – terwyl u die wit plasebo tablette neem – maar u mag ligte of menstruasie-agtige bloeding tydens die tweede stulpstrook ervaar.
2. U kan ook ophou om die pienk aktiewe tablette te neem en dadelik na die wit plasebo tablette oorskakel (voor u die wit plasebo tablette neem, maak 'n aantekening van die dag waarop u die tablet vergeet het). Indien u 'n nuwe stulpstrook wil begin gebruik op die dag waarop u altyd begin, gebruik die wit plasebo tablette vir minder as 4 dae.

Indien u een van hierdie twee aanbevelings volg sal u steeds teen swangerskap beskerm wees.

Indien u enige tablette op 'n stulpstrook vergeet het, en u bloei nie tydens die plasebo dae nie, kan dit beteken dat u swanger kan wees. U moet u dokter kontak voordat u die volgende stulpstrook begin.

Skedule vir wanneer u meer as 24 ure laat is met die neem van die pienk aktiewe tablette



Meer as een vergete tablet op hierdie stulpstrook
Volg die advies van u dokter.

Indien u braak of erge diarree het

Indien u binne 3-4 ure na die neem van ’n pienk aktiewe tablet braak of erge diarree ervaar, is daar ’n risiko dat die aktiewe bestanddele in die pil nie ten volle deur u liggaam opgeneem is nie. Die situasie is amper dieselfde as om ’n tablet te vergeet. Na braking en diarree moet u so gou as moontlik nog ’n pienk aktiewe tablet van ’n reserwe stulpstrook neem. Neem dit binne 24 uur of wanneer u normaalweg u pil neem. Indien dit nie moontlik is nie, of 24 uur het verstryk, moet u die raad onder ‘Indien u vergeet om DROVELIS te gebruik’ volg.

Vertraging van menstruasie: wat u moet weet
U kan u menstruasie vertraag, al word dit nie aanbeveel nie, deur nie die wit plasebo tablette van die 4de ry te neem nie en direk na ’n nuwe stulpstrook van DROVELIS oor te gaan en dit te voltooi. U mag ligte of menstruasie-agtige bloeding tydens gebruik van die tweede stulpstrook ervaar. Voltooi die tweede stulpstrook deur die 4 wit plasebo tablette te neem. Begin dan met die volgende stulpstrook. U mag u dokter vir advies vra voor u besluit om u menstruasie te vertraag.

Indien u die eerste dag van u menstruasie wil verander
Indien u die tablette volgens die instruksies gebruik sal u menstruasie tydens die plasebo dae begin. Indien u hier dag moet verander, verminder die aantal plasebo dae – wanneer u die wit plasebo tablette neem – maar moet dit nooit vermeerder nie (4 is die maksimum). Byvoorbeeld, indien u die wit plasebo tablette op Vrydag neem en u wil dit na Dinsdag verander (3 dae vroeër) moet u ’n nuwe stulpstrook 3 dae vroeër indien normaal begin. U mag dalk nie tydens die verkorte periode van die neem van die wit plasebo tablette menstrueer nie. U mag dalk ‘n bietjie kolbloeding (’n paar bloeddruppels of vlekkies) of deurbraak-bloeding tydens die dae wanneer u die pienk aktiewe tablette neem ervaar.

Praat met u dokter of apteker indien u nie seker is oor wat om te doen nie.

Indien u die gebruik van DROVELIS staak
U kan die gebruik van DROVELIS enige tyd staak. Indien u nie swanger wil raak nie, vra eers u dokter oor ander metodes van geboortebeperking.

Indien u ophou om DROVELIS gebruik omdat u swanger wil raak is dit die beste om te wag totdat u natuurlik menstrueer voordat u probeer om swanger te raak. Dit sal u help om die verwagte geboortedatum makliker te bereken.

Raadpleeg u dokter of apteker indien u enige verdere vrae het oor die gebruik van DROVELIS.

4. Moontlike newe-effekte
DROVELIS kan newe-effekte hê.

Nie alle newe-effekte wat vir DROVELIS aangemeld is word in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u gesondheidsorgverskaffer vir advies indien u algemene gesondheid verswak of u enige ongewenste effekte ervaar tydens die gebruik van DROVELIS.

’n Verhoogde risiko van bloedklonte in u are (VTE) of bloedklonte in u slagare (ATE) is teenwoordig vir alle vroue wat saamgestelde hormonale voorbehoedmiddels gebruik. Sien asseblief afdeling 2 ‘Wat u moet weet voordat u DROVELIS gebruik’ vir meer volledige inligting oor die verskillende risiko’s van die gebruik van saamgestelde hormonale voorbehoedmiddels.

Staak die gebruik van DROVELIS en lig u dokter onmiddellik in of gaan na die ongevalle afdeling by u naaste hospitaal indien enige van volgende gebeur:
- swelling van u hande, voete, enkels, gesig, lippe mond of keel, wat sluk en asemhaling bemoeilik,
- veluitslag of jeukerigheid.

Hierdie is alles baie ernstige newe-effekte. Indien u hulle ervaar, het u dalk ’n ernstige allergiese reaksie vir DROVELIS gehad het. U mag dringende mediese sorg of hospitalisasie benodig.
Lig u dokter in indien u enige van die volgende opmerk:
Newe-effekte wat algemeen voorkom:

- gemoedsversteuring, libido versteuring
- hoofpyn
- abdominale pyn, naarheid
- aknee
- borspyn, pynlike menstruasie, vaginale bloeding (gedurende of buite menstruasies, swaar ongereelde bloeding)
- wisseling in gewig

Newe-effekte wat minder algemeen voorkom:

- swaminfeksie, vaginale infeksie, urienweginfeksie
- verandering in eetlus (eetlusversteuring)
- depressie, emosionele versteuring, angsversteuring, stres, probleme om te slaap
- migraine, duiseligheid, ‘naalde-en-spelde’, lomerigheid
- warm gloede
- abdominale (buik)-swelling, braking, diarree
- haarverlies, oormatige sweet (hiperhidrose), droë vel, veluitslag, swelling van die vel
- rugpyn
- geswelde borste, knoppe in die bors, abnormale bloeding van die geslagsdele, pyn tydens gemeenskap, fibrosistiese borssiekte (teenwoordigheid van een of meer siste in ’n bors), swaar menstruasie, geen menstruasie, menstruele versteurings, pre-menstruale sindroom, kontraksies van die uterus, uterus- of vaginale bloeding insluitend kolbloeding, vaginale afskeiding, vulvovaginale versteurings (droogheid, pyn, slegte reuk, ongemak)
- moegheid, swelling van dele van u liggaam, bv. enkels (edeem), borspyn, abnormaal voel
- bloedtoetse wys verhoogde lewerensiemvlakke, verandering in sekere bloedvette (lipiede)
- inflammasie in die bors
- nie-kwaadaardige bors massa
- vloeistof retensie, verhoogde kaliumvlakke in die bloed
- senuweeagtigheid
- vergeetagtigheid
- droë oë, versteurde visie, verswakte sig
- vertigo (’n sensasie dat u of u omgewing draai of beweeg)
- hoë of lae bloeddruk, inflammasie van ’n aar met die vorming van ’n bloedklont (tromboflebitis), spataar
- hardlywigheid, droë mond, slegte spysvertering, swelling van die lippe, winderigheid, inflammasie in die derms, gastriese refluks, abnormale saamtrekking van die derms
- allergiese velreaksies, goudbruin pigmentvlekke (chloasma) en ander pigmentasie versteurings, manlike-patroon haargroei, oormatige haargroei, veltoestande soos dermatitis en jeukende dermatitis, skilfers en olierige vel (seborree) en ander versteurings van die vel
- spier- en gewrigkrampe, pyn en ongemak
- urienwegpyn, urien wat abnormaal ruik
- swangerskap wat buite die baarmoeder voorkom (ektopiese swangerskap)
- sist op die eierstokke, verhoogde spontane melkvloei, pyn van die pelvis, verkleuring van borste, bloeding tydens gemeenskap, endometriale versteurings, versteurings van die tepels, abnormale bloeding van die uterus
- malaise en algemene onwel gevoel, verhoogde liggaamstemperatuur, pyn
- verhoogde bloeddruk, verandering in bloedtoetse (abnormale nierfunksie toets,

verhoogde bloedkaliumvlakke, verhoogde bloedglukosevlakke, verminderde hemoglobien, verminderde ysterreserwes in die bloed, bloed in die urien)
- skadelike bloedklonte in ’n aar byvoorbeeld
  - in ’n been of voet (d.i. DVT)
  - in ’n long (d.i. PE)
  - hartaanval
  - beroerte
  - mini-beroerte of tydelike beroerte-agtige simptome, bekend indien tydelike iskemiese aanval (TIA)
  - bloedklonte in die lewer, maag/derms, niere of oë

  Die kans om ’n bloedklont te kry kan hoër wees indien u enige ander toestand het wat hierdie risiko verhoog (sien afdeling 2 vir meer inligting oor die toestande wat die risiko vir bloedklontvorming en die simptome van ’n bloedklont verhoog).

Indien u enige newe-effekte wat nie in hierdie voubiljet genoem word nie, opmerk, stel u dokter of apteker in kennis.

Aanmelding van newe-effekte
Raadpleeg u dokter of apteker indien u newe-effekte ervaar. U kan newe-effekte ook by SAHPRA aanmeld via die vorm “**6.04 Adverse Drug Reactions Reporting Form**”, wat aanlyn gevind kan word onder SAHPRA se publikasies: http://www.sahpra.org.za/Publications/Index/8.

Deur newe-effekte aan te meld kan u help om meer inligting oor die veiligheid van DROVELIS te verskaf.

5. Hoe om DROVELIS te bêre
- Bêre teen of benede 25 °C.
- Hou die stulpstrook in die buitenste kartonboksie om dit teen lig te beskerm.
- Bêre alle medisyne buite bereik van kinders.
- Moenie ná die vervaldatum, wat of die kartonboksie gedruk is, gebruik nie.
- Neem alle ongebruikte medisyne na u apteker terug.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van die verpakking en ander inligting
Wat DROVELIS bevat
Elke pienk aktiewe tablet bevat 3 mg drospirenoon en estetrolmonohidraat gelykstaande aan 14,2 mg estetrol.

Elke wit plasebo tablet bevat geen aktiewe bestanddele nie.

Pienk aktiewe filmbedekte tablette:
Tablet-kern:
Laktosemonohidraat, natriumstyselglikonaat, mieliestysel, povidoon K30, magnesiumstearaat (E470b).
Tablet-bedekking:
Hipromellose (E464), hidroksiepropielsellulose (E463), talk (E553b), gehidrogeneerde katoensaadolie, titaandioksied (E171), ysteroksied rooi (E172).

Wit plasebo filmbedekte tablette:
Tablet kern:
Laktose-monohidraat, mieliestysel, magnesiumstearaat (E470b).
Tablet bedekking:
Hipromellose (E464), hidroksiepropielsellulose (E463), talk (E553b), gehidronigeerde katoensaadolie, titaandioksied (E171).

PASIËNT INLIGTINGSBILJET

Hoe DROVELIS lyk en inhoud van die verpakking
Die aktiewe filmbedekte tablette is pienk, 6 mm in deursnee, rond, bikonveks met 'n druppelvormige logo op die een kant gedruk.

Die plasebo filmbedekte tablette is wit tot naaswit, 6 mm in deursnee, rond, bikonveks met 'n druppelvormige logo op die een kant gedruk.

DROVELIS kom verskaf in deurskynende PVC/aluminium stulpstroke met 28 filmbedekte tablette (24 pienk aktiewe tablette en 4 wit plasebo tablette) in 'n kartonboksie verpak. Bykomend tot die stulpstrook(e) bevat die DROVELIS kartonboksie 'n klein bêre-sakkie en 1, 3, 6, of 13 self-klewende plakker(s), gemerk met die dae van die week. Die aantal self-klewende plakkers hang van die aantal stulpstroke af.

Verpakkingsgroottes: 28 (1 × 28), 84 (3 × 28), 168 (6 × 28) en 364 (13 × 28) filmbedekte tablette.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die registrasiesertifikaat
Adcock Ingram Limited
New Road 1,
Erand Gardens,
Midrand, 1685
Kliëntediens: 0860 ADCOCK / 232625

Hierdie voubiljet is mees onlangs hersien op
30 Julie 2024

Registrasienommer
56/18.8/0933

adcock ingram
51758297 08/2024

Datum van goedkeuring: 30 Julie 2024