

**SCHEDULING STATUS:** **S4**

**NEOLED® 2,5 & 5 & 7,5 & 10 & 15 & 20 & 25 mg (hard gelatine capsule)  
Lenalidomide**

**NEOLED 2,5 mg contains sugar (lactose) 33,2 mg per capsule**

**NEOLED 5 mg contains sugar (lactose) 66,4 mg per capsule**

**NEOLED 7,5 mg contains sugar (lactose) 99,7 mg per capsule**

**NEOLED 10 mg contains sugar (lactose) 132,9 mg per capsule**

**NEOLED 15 mg contains sugar (lactose) 199,3 mg per capsule**

**NEOLED 20 mg contains sugar (lactose) 265,8 mg per capsule**

**NEOLED 25 mg contains sugar (lactose) 332,2 mg per capsule**

**Read all of this leaflet carefully before you start taking NEOLED**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- NEOLED 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 NEOLED is and what it is used for
2. What you need to know before you take NEOLED
3. How to take NEOLED
4. Possible side effects
5. How to store NEOLED
6. Contents of the pack and other information

**1. What NEOLED is and what it is used for**

NEOLED contains the active substance lenalidomide. This medicine belongs to a group of medicines which affect how your immune system works.

NEOLED is used in adults for:

**Multiple myeloma – in patients who have had treatment before**

- NEOLED is taken together with an anti-inflammatory medicine called 'dexamethasone'.
- NEOLED can stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

**Myelodysplastic syndromes**

MDS are a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly. Patients can experience a variety of signs and symptoms including a low red blood cell count (anaemia), the need for a blood transfusion, and be at risk of infection.

NEOLED is used alone to treat adult patients who have been diagnosed with MDS, when all of the following apply:

- you need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anaemia')
- you have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells
- other treatments have been used before, are not suitable or do not work well enough.

## 2. What you need to know before you take NEOLED

### Do not take NEOLED:

- if you are hypersensitive (allergic) to lenalidomide or any of the other ingredients of NEOLED (listed in Section 6).
- if you are pregnant, think you may be pregnant or are planning to become pregnant, as NEOLED is expected to be harmful to an unborn child (see section 2, Pregnancy, breastfeeding and fertility).
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see section 2, Pregnancy, breastfeeding and fertility – information for women and men). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and provide you with this confirmation.

### Warnings and precautions

Take special care with NEOLED:

- if you have had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels
- if you have had blood clots in the past - you have an increased risk of developing blood clots in the veins and arteries during treatment
- if you have any thyroid problems
- if you have had an allergic reaction whilst taking thalidomide (another medicine used to treat multiple myeloma) such as rash, itching, swelling, dizziness or trouble breathing
- if you have experienced in the past a combination of any of the following symptoms: widespread rash, red skin, high body temperature, flu-like symptoms, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes – these are signs of a severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome. (see section 4 “Possible side effects”).
- if you have liver problems
- if you have kidney problems - your doctor may adjust your dose of NEOLED
- if you have any signs of an infection, such as a cough or fever
- if you have or have ever had previous viral infection, particularly: hepatitis B infection, varicella zoster, HIV. If you are in doubt, talk to your doctor. Treatment with NEOLED may cause the virus to become active again, in patients who carry the virus. This results in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.
- if you experience clouding of your eye (cataract)

If any of the above apply to you, tell your doctor, pharmacist or nurse before starting treatment.

Your doctor may check if you have a high total amount of tumour throughout the body, including your bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood which can lead to kidney failure (this condition is called ‘Tumour Lysis Syndrome’).

At any time during or after your treatment, tell your doctor or nurse immediately if you: experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.

These may all be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML). If you had these symptoms prior to treatment with NEOLED, tell your doctor about any change in these symptoms.

### **Tests and checks**

Before and during the treatment with NEOLED you will have regular blood tests. This is because NEOLED may cause a fall in the blood cells that help fight infection (white blood cells) and help the blood to clot (platelets).

Your doctor will ask you to have a blood test:

- before treatment
- every week for the first 8 weeks of treatment
- then at least every month after that.

### *For patients with MDS taking NEOLED*

If you have MDS, you may be more likely to get a more advanced condition called acute myeloid leukaemia (AML). In addition, it is not known how NEOLED affects the chances of you getting AML. Your doctor may therefore do tests to check for signs which may better predict the likelihood of you getting AML during your treatment with NEOLED.

Your doctor may check you for changes to your skin such as red spots or rashes.

Your doctor may adjust your dose of NEOLED or stop your treatment based on the results of your blood tests and on your general condition.

### **Blood donation**

You should not donate blood during treatment and for at least 4 weeks after the end of treatment.

### **Children and adolescents**

Do not give NEOLED to children under the age of 18 years.

### **Other medicines and NEOLED**

Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- medicines which stimulates the bone marrow to make red blood cells
- hormone replacement therapy
- some medicines used to prevent pregnancy such as oral contraceptives, as they may stop working
- some medicines used to thin the blood – such as warfarin.
- some medicines used for heart problems – such as digoxin
- some medicines for high cholesterol -such as statins

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking NEOLED.

**You must not take NEOLED if you are pregnant or breastfeeding your baby) (see sections 4.3 and 4.4).**

## **Pregnancy**

### *For women taking NEOLED*

- You must not take NEOLED if you are pregnant, as it is expected to be harmful to an unborn baby.
- You must not become pregnant while taking NEOLED. Therefore, you must use effective methods of contraception if you are a woman of childbearing potential (see 'Contraception').
- If you do become pregnant during your treatment with NEOLED, you must stop the treatment and inform your doctor immediately.

### *For men taking NEOLED*

- If your partner becomes pregnant whilst you are taking NEOLED, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.
- You must also use effective methods of contraception (see 'Contraception').

## **Contraception**

### *For women taking NEOLED*

Before starting the treatment, ask your doctor if you are able to become pregnant, even if you think this is unlikely.

If you are able to become pregnant

- you will have pregnancy tests under the supervision of your doctor (before every treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished) except where it has been confirmed that the fallopian tubes have been severed and sealed, to stop eggs from reaching the uterus (tubal sterilisation)

AND

- you must use effective methods of contraception for at least 4 weeks before starting treatment, during treatment, and until at least 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

### *For men taking NEOLED*

NEOLED passes into human semen. If your female partner is pregnant or able to become pregnant, and she does not use effective methods of contraception, you must use condoms during treatment and for at least 4 weeks after the end of treatment, even if you have had a vasectomy.

## **Driving and using machines**

NEOLED can make you feel dizzy, tired, sleepy or you can have vertigo or blurred vision.

It is not always possible to predict to what extent NEOLED may interfere with the daily activities of a patient. You should ensure that you do not engage in the driving of a vehicle or use machines until you are aware of the measure to which NEOLED affects you.

## **NEOLED contains sugar (lactose).**

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking NEOLED.

## **3. How to take NEOLED**

Do not share medicines prescribed for you with any other person.

Always take NEOLED exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

***Myelodysplastic syndromes (MDS)***

The usual starting dose of NEOLED is 10 mg given orally once a day on days 1-21 of repeating 28-day treatment cycles.

***Multiple myeloma***

The usual starting dose of NEOLED when treating multiple myeloma in patients who have had other treatments before is 25 mg per day, taken orally and NEOLED is taken with other medicines. You should refer to the package leaflets for these medicines for further information on their use and effects.

***Treatment cycle***

NEOLED is taken on certain days over 3 weeks (21 days).

- Every 21 days is called a 'treatment cycle'.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.
- After completing every 21-day cycle, you should start a new 'cycle' over the next 21 days.

OR

NEOLED is taken on certain days over 4 weeks (28 days).

- Every 28 days is called a 'treatment cycle'.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.
- After completing every 28-day cycle, you should start a new 'cycle' over the next 28 days.

***How much NEOLED to take***

Before you start treatment, your doctor will tell you:

- how much NEOLED you should take
- how much of the other medicines you should take in combination with NEOLED, if any
- on what days of your treatment cycle to take each medicine.

***How and when to take NEOLED***

- swallow the capsules whole, preferably with water.
- do not break, open or chew the capsules. If powder from a broken NEOLED capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- the capsules can be taken either with or without food.
- you should take NEOLED at about the same time on the scheduled days.

***If you take more NEOLED than you should***

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

***If you forget to take NEOLED***

Do not take a double dose to make up for forgotten individual doses.

***If you stop taking NEOLED***

Do not stop taking NEOLED or change your dose without talking to your doctor first. Your doctor will decide on the duration of the treatment.

**4. Possible side effects**

NEOLED can have side effects.

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

If any of the following happens, stop taking NEOLED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).
- serious allergic reaction that may begin as a rash in one area but spread with extensive loss of skin over the whole body (Stevens-Johnson syndrome and/or toxic epidermal necrolysis)

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection including within the bloodstream (sepsis)
- bleeding or bruising in the absence of injury
- chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting, which may be symptoms of a heart attack (myocardial infarction)
- leg pain (which could be a symptom of thrombosis), chest pain or shortness of breath (which may be a symptom of blood clots in the lungs, called pulmonary embolism)
- widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

### *Frequent*

- fever and flu like symptoms including fever, runny nose, sore throat, muscle ache, headache, earache and chills
- constipation, diarrhoea, nausea, vomiting
- toothache
- dry mouth, stomach pain, indigestion
- muscle cramps, muscle weakness, muscle pain, muscle aches, bone pain, joint pain, back pain, pain in the extremities, tiredness, fever, generalised swelling including swelling of your arms and legs
- numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor, changes in taste
- stroke
- nose bleeds, shortness of breath, infection of the upper respiratory tract
- infections of all types
- infection of the lung and the upper respiratory tract, sinus infection
- dry skin, excessive sweating
- a fall in the number of red blood cells which may cause anaemia leading to tiredness and weakness
- underactive thyroid gland

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- decreased appetite
- increases in your blood sugar level (diabetes)
- low levels of potassium and/or sodium in the blood
- low levels of calcium, phosphate or magnesium in the blood
- dehydration
- an excess of iron in the body
- blurred vision
- clouding of your eye (cataract)
- kidney failure
- low or high blood pressure
- a solid swelling of clotted blood within the tissues
- depression, altered mood
- an irregular, rapid heart rate that may cause symptoms like heart palpitations, fatigue, and shortness of breath
- blood cancers
- increase in liver test results
- decreased weight
- fall

### *Less frequent*

- Hypersensitivity

### *Unknown frequency*

- viral infections, including herpes zoster (also known as 'shingles', a viral disease that causes a painful skin rash with blisters) and recurrence of hepatitis B infection (which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided stomach pain, fever and feeling nauseous or being sick).
- potentially life-threatening bleeding disorder
- rejection of solid organ transplant (such as kidney, heart)
- wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs
- sudden, or mild but worsening pain in the upper stomach and/or back, which remains for a few days, possibly accompanied by nausea, vomiting, fever and a rapid pulse – these symptoms may be due to inflammation of the pancreas.
- breakdown of the wall of the stomach or gut. This may lead to very serious infection. Tell your doctor if you have severe stomach pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits.
- yellow pigmentation to the skin, mucus membrane or eyes (jaundice), pale coloured stools, dark coloured urine, skin itch, rash, pain or swelling of the stomach – these may be symptoms of injury to the liver (hepatic disorder).
- A condition affecting the skin caused by inflammation of small blood vessels, along with pain in the joints and fever (leukocytoclastic vasculitis).
- Tumour lysis syndrome - metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the break-down products of dying cancer cells and may include the following: changes to blood chemistry – high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of NEOLED.

### **5. How to store NEOLED**

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep the capsule in the blister in the outer carton until required for use.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What NEOLED contains**

The active substance is lenalidomide.

The other ingredients are cellulose; microcrystalline, croscarmellose sodium, lactose magnesium stearate.

#### *Capsule shell:*

#### NEOLED 2,5 & 10 & 20 mg

Gelatine, Indigotine – FD&C Blue #2 (E132), titanium dioxide (E171), yellow iron oxide (E172).

#### NEOLED 5 & 25 mg

Gelatine, titanium dioxide (E171).

#### NEOLED 7,5 mg

Gelatine, titanium dioxide (E171), yellow iron oxide (E172).

*Capsule ink:* Iron oxide black (E172), potassium hydroxide (E525), propylene glycol (E1520), shellac (E904), strong ammonia solution (E527).

#### NEOLED 15 mg

Gelatine, titanium dioxide (E171), Indigotine – FD&C Blue #2 (E132)

#### **What NEOLED looks like and contents of the pack**

#### *NEOLED 2, 5 mg (hard capsules)*

Hard gelatine capsule, with an opaque white body and opaque green cap with “L9NL” and “2.5” printed radial on body. Capsule size: 4

#### *NEOLED 5 mg (hard capsules)*

Hard gelatine capsule, with an opaque white body and opaque white cap with “L9NL” and “5” printed radial on body. Capsule size: 2

#### *NEOLED 7,5 mg (hard capsules)*

Hard gelatine capsule, with an opaque white body and opaque yellow cap with “L9NL” and “7.5” printed radial on body. Capsule size: 2

#### *NEOLED 10 mg (hard capsules)*

Hard gelatine capsule, with an opaque yellow body and opaque green cap with “L9NL” and “10” printed radial on body. Capsule size: 0

#### *NEOLED 15 mg (hard capsules)*

Hard gelatine capsule, with an opaque white body and opaque blue cap with “L9NL” and “15” printed radial on body. Capsule size: 0

#### *NEOLED 20 mg (hard capsules)*

Hard gelatine capsule, with an opaque blue body and opaque green cap with “L9NL” and “20” printed radial on body. Capsule size: 0

#### *NEOLED 25 mg (hard capsules)*

Hard gelatine capsule, with an opaque white body and opaque white cap with “L9NL” and “25” printed radial on body. Capsule size: 0



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The capsules are packed in an oPA/Al/PVC/Al blisters (packed in carton boxes).

### **Holder of Certificate of Registration**

Adcock Ingram Limited  
1 New Road  
Midrand  
1685  
Customer care: 0860 ADCOCK /232625

### **This leaflet was last revised in**

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### **Registration/ Application number**

Neoled 2,5 mg 54/32/0540  
Neoled 5 mg 54/32/0541  
Neoled 7,5 mg 54/32/0542  
Neoled 10 mg 54/32/0543  
Neoled 15 mg 54/32/0544  
Neoled 20 mg 54/32/0545  
Neoled 25 mg 54/32/0546

**SKEDULERINGSSTATUS: S4**

**NEOLED® 2,5 & 5 & 7,5 & 10 & 15 & 20 & 25 mg (harde gelatienkapsule)  
Lenalidomied**

**NEOLED 2,5 mg bevat suiker (laktose) 33,2 mg per kapsule**

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**NEOLED 25 mg bevat suiker (laktose) 332,2 mg per kapsule**

**Lees hierdie voubiljet noukeurig voordat u NEOLED begin gebruik**

- Hou hierdie voubiljet. U mag dit weer moet lees.
- Vra u dokter, apteker, verpleegster of ander gesondheidsorgverskaffer as u enige verdere vrae het.
- NEOLED is aan u persoonlik voorgeskryf en u moet nie u medisyne met enige ander mense deel nie. Dit mag hulle skaad, selfs as hulle dieselfde simptome as u het.

**Wat in hierdie voubiljet is**

1. Wat NEOLED is en waarvoor dit gebruik word
2. Wat u moet weet voordat u NEOLED gebruik
3. Hoe om NEOLED te gebruik
4. Moontlike nuwe-effekte
5. Hoe om NEOLED te bêre
6. Inhoud van pak en ander inligting

**1. Wat NEOLED is en waarvoor dit gebruik word**

NEOLED bevat die aktiewe bestanddeel lenalidomied. Hierdie medisyne behoort aan 'n groep van medisyne wat die werking van die immuunstelsel beïnvloed.

NEOLED word deur volwassenes gebruik vir:

**Veelvoudige miëlloom – vir pasiënte wie voorheen behandeling ontvang het**

- NEOLED word saam met 'n ander inflammatoriese middel genaamd 'deksametasoon' gebruik.
- NEOLED kan die tekens en simptome van miëlloom stop. Dit het ook getoon om terugkeer van veelvoudige miëlloom na behandeling te vertraag.

**Miëlodisplastiese sindrome**

MDS is 'n versameling van baie verskillende bloed- en beenmurg siektes. Die bloedselle raak abnormaal en funksioneer nie behoorlik nie. Pasiënte kan 'n verskeidenheid tekens en simptome ervaar, wat 'n lae rooibloedseltelling (bloedarmoede), die behoefte vir 'n bloedoortapping, en die risiko vir infeksie insluit.

NEOLED word alleen gebruik om volwassenes wie met MDS gediagnoseer is te behandel, wanneer al die volgende van toepassing is:

- u gereeld bloedoortappings om lae rooibloedsel-vlakke te behandel ('oorplanting-afhanklike bloedarmoede)
- u het 'n abnormaliteit van selle in die beenmurg wat 'n 'geïsoleerde skrapping 5q sitogenetiese abnormaliteit' genoem word. Dit beteken u liggaam maak nie genoeg gesonde bloedselle nie
- ander behandelinge wat voorheen gebruik is, is nie geskik nie of werk nie voldoende nie.

## 2. Wat u moet weet voordat u NEOLED gebruik

### Moenie NEOLED gebruik nie:

- as u hipersensitief (allergies) is vir lenalidomied of enige van die ander bestanddele van NEOLED ( in Afdeling 6 gelys).
- as u swanger is, dink u is swanger of u beplan om swanger te raak, aangesien dit ver wag word dat NEOLED skadelik vir ongebore babas kan wees (sien afdeling 2, Swangerskap, borsvoeding en vrugbaarheid).
- as u swanger kan raak, tensy u die volgende maatreëls volg om swangerskap te voorkom (sien afdeling 2, Swangerskap, borsvoeding en vrugbaarheid – inligting vir vroue en mans). U dokter sal met elke voorskrif aanteken dat die verlangde maatreëls gevolg is en u van bevestiging daarvan voorsien as u swanger kan raak.

### Waarskuwings en voorsorgmaatreëls

Neem spesiale voorsorg met NEOLED:

- as u 'n hartaanval gehad het, ooit 'n bloedklont gehad het, of as u rook, of hoë bloeddruk of hoë cholesterolvlakke het
- as u in die verlede bloedklonte gehad het – u loop 'n verhoogde risiko om bloedklonte in die are en slagare tydens behandeling te ontwikkel
- as u skildklierprobleme het
- as u 'n allergiese reaksie tydens gebruik van talidomied ('n ander medisyne vir veelvoudige miëlom) gehad het, soos uitslag, jeuking, swelling, duiseligheid of asemhalingsprobleme
- as u in die verlede 'n kombinasie van enige van die volgende simptome ervaar het: wydverspreide uitslag, rooi vel, hoë liggaamstemperatuur, griepagtige simptome, verhoogde lewer-ensiemvlakke, abnormaliteite van die bloed (eosinofilie), geswelde limfkliere – hierdie is tekens van 'n ernstige velreaksie wat Geneesmiddelreaksie met eosinofilie en sistemiese simptome, ook DRESS of geneesmiddel-hipersensitiwiteit-sindroom, genoem word. (sien afdeling 4 “Moontlike newe-effekte”).
- as u lewerprobleme het
- as u nierprobleme het – u dokter mag u dosis van NEOLED aanpas
- as u enige tekens van 'n infeksie soos hoes of koors toon
- as u enige virale infeksie het of ooit gehad het, veral; hepatitis B infeksie, varicella zoster, MIV. Praat met u dokter as u twyfel. Behandeling met NEOLED kan veroorsaak dat die virus weer by pasiënte wie die virus dra, aktief raak. Dit veroorsaak 'n herhaling van die infeksie. U dokter behoort te bevestig of u ooit hepatitis B infeksie gehad het.
- as u vertroebeling van u oog ervaar (katarak)

Vertel u dokter, apteker of verpleegster as enige van die bogenoemde op u van toepassing is voordat u met die behandeling begin.

U dokter mag bevestig of u 'n hoë totale aantal gewasse regdeur u liggaam het, u beenmurg ingesluit. Dit kan tot 'n toestand lei wat die afbreek en ongewone vlakke van chemikalieë tot gevolg kan hê wat tot nierversaking kan lei (hierdie toestand word “Tumor Lysis Sindroom” genoem).

Vertel u dokter of verpleegster onmiddellik te enige tyd tydens of na u behandeling as u: versteurde visie, dubbel visie of sig verlies, moeite om te praat, swakheid van 'n arm of been, 'n verandering in die manier waarop u loop of probleme met u balans, voortdurende

gevoelloosheid, verminderde sensasie of verlies van sensasie, geheueverlies of verwarring ervaar.

Hierdie kan almal simptome van 'n ernstige en potensieel dodelike breintoestand bekend as progressiewe multi-fokale leuko-enkefalopatie (PML) wees. As u hierdie simptome voor die behandeling met NEOLED ervaar het, vertel u dokter van enige verandering in hierdie simptome.

### **Toetse en kontrole**

U sal gereelde bloedtoetse ondergaan voor en gedurende behandeling met NEOLED. Dit is omdat NEOLED 'n afname in die bloedselle wat help om infeksie te beveg (wit bloedselle) en help om die bloed te laat stol (plaatjies) kan veroorsaak.

U dokter sal u vra om 'n bloedtoets te ondergaan:

- voor behandeling
- elke week vir die eerste 8 weke van behandeling
- dan ten minste elke maand daarna.

### *Vir pasiënte met MDS wie NEOLED gebruik*

U mag meer geneig wees om 'n meer gevorderde toestand genaamd akute miëloïde leukemie (AML) te kry as u MDS het. Daarbenewens is dit onbekend hoe NEOLED die kans vir u om AML te kry beïnvloed. Daarom kan u dokter toetse doen om tekens wat die waarskynlikheid dat u AML tydens behandeling met NEOLED kan kry te bevestig.

U dokter mag u ondersoek vir veranderinge in u vel soos rooi kolle of uitslag.

U dokter kan u dosis van NEOLED aanpas of u behandeling staak gebaseer op die uitslag van u bloedtoetse en u algemene gesondheid.

### **Bloedskenking**

U moenie bloed skenk tydens behandeling en vir ten minste 4 weke na die einde van behandeling nie.

### **Kinders en adolessente**

Moenie NEOLED aan kinders onder 18 jaar oud gee nie.

### **Ander medisyne en NEOLED**

Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit aanvullende en tradisionele medisyne in.)

Vertel u dokter as u enige van die volgende medisyne gebruik:

- medisyne wat die beenmurg stimuleer om rooibloedselle te maak
- hormoonvervangingsterapie
- sommige medisyne wat gebruik word om swangerskap te voorkom soos orale voorbehoedmiddels, aangesien hulle kan ophou om te werk
- sommige medisyne wat gebruik word om die bloed te verdun - soos warfarin.
- Sommige medisyne wat vir hartprobleme gebruik word - soos digoxin
- Sommige medisyne vir hoë cholesterol - soos statiene

### **Swangerskap, borsvoeding en vrugbaarheid**

Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir raad voordat u NEOLED gebruik as u swanger is of borsvoed, dink u mag dalk swanger wees of beplan om 'n baba te hê.

**U moenie NEOLED gebruik as u swanger is of u baba borsvoed nie (sien afdelings 4.3 en 4.4).**

### **Swangerskap**

*Vir vroue wie NEOLED gebruik*

- U moenie NEOLED gebruik as u swanger is nie, aangesien dit vermag word om skadelik vir u ongebore baba te wees.
- U moenie swanger raak terwyl u NEOLED gebruik nie. U moet daarom effektiewe voorbehoedingsmetodes gebruik as u 'n vrou van vrugbare potensiaal is (sien 'Voorbehoeding').
- As u tydens behandeling met NEOLED swanger raak, moet u die behandeling onmiddellik staak en u dokter in kennis stel.

*Vir mans wie NEOLED gebruik*

- As u maat swanger raak terwyl u NEOLED gebruik, moet u u dokter onmiddellik in kennis stel. Dit word aanbeveel dat u maat mediese advies bekom.
- U moet ook effektiewe voorbehoedingsmetodes gebruik (sien "Voorbehoeding").

### **Voorbehoeding**

*Vir vroue wie NEOLED gebruik*

Vra u dokter of u swanger kan raak, selfs as u dink dis onwaarskynlik, voordat u die behandeling begin.

As u swanger kan raak

- u sal swangerskaptoetse onder toesig van u dokter ondergaan (voor elke behandeling, ten minste elke 4 weke gedurende behandeling, en ten minste 4 weke na die behandeling geëindig het) behalwe waar dit bevestig is dat die fallopiese buise geknip en geseël is om te voorkom dat eierselle die baarmoeder bereik (buis-sterilisasie)

EN

- u moet effektiewe voorbehoedingsmetodes gebruik vir ten minste 4 weke na staking van behandeling. U dokter sal u oor gepaste metodes van voorbehoeding inlig.

*Vir mans wie NEOLED gebruik*

NEOLED word oorgedra na menslike semen. As u vroulike maat swanger is of kan swanger kan raak, en sy gebruik nie effektiewe voorbehoedingsmetodes nie, dan moet u kondome tydens behandeling en vir ten minste 4 weke na die behandeling beëindig is gebruik, selfs al het u 'n vasektomie gehad.

### **Bestuur en bedryf van masjinerie**

NEOLED kan u duiselig, moeg of lomerig laat voel of u kan vertigo of versteurde visie ervaar.

Dit is nie altyd moontlik om te voorspel tot watter mate NEOLED by die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. U moet seker maak dat u nie 'n voertuig bestuur of masjinerie bedryf totdat u seker is van die mate waartoe NEOLED u beïnvloed nie.

### **NEOLED bevat suiker (laktose).**

As u deur u dokter ingelig is dat u 'n onverdraagbaarheid vir sekere suikers het, kontak u dokter voordat u NEOLED gebruik.

### **3. Hoe om NEOLED te gebruik**

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.

Gebruik NEOLED altyd presies soos u dokter voorgeskryf het. Bevestig met u dokter of apteker as u nie seker is nie.

***Miëlodisplastiese sindrome (MDS)***

Die gewone aanvangsdosis van NEOLED is 10 mg mondeliks toegedien een keer per dag op dae 1-21 van herhalende 28-dag behandelingsiklusse.

***Veelvoudige miëlloom***

Die gewone aanvangsdosis van NEOLED tydens behandeling vir veelvoudige miëlloom vir pasiënte wie voorheen ander behandelings gehad het is 25 mg per dag, mondeliks geneem, as NEOLED saam met ander medisynes gebruik word. U moet na die voubiljette van hierdie ander medisynes verwys vir meer inligting oor hulle gebruike en invloede.

***Behandelingsiklus***

NEOLED word op sekere dae oor 3 weke (21 dae) gebruik.

- Elke 21 dae word 'n 'behandelingsiklus' genoem.
- Afhangende van die dag van die siklus, sal u een of meer van die medisyne neem. Op sekere dae neem u egter geen van die medisyne nie.
- Na voltooiing van elke 21-dag siklus moet u 'n nuwe siklus oor die volgende 21 dae begin.

OF

NEOLED word op sekere dae oor 4 weke (28 dae) geneem.

- Elke 28 dae word 'n 'behandelingsiklus' genoem.
- Afhangende van die dag van die siklus, sal u een of meer van die medisyne neem. Op sekere dae neem u egter geen van die medisyne nie.
- Na voltooiing van elke 28-dag siklus moet u 'n nuwe siklus oor die volgende 28 dae begin.

***Hoeveel NEOLED om te gebruik***

U dokter sal u inlig voor u behandeling begin:

- hoeveel NEOLED u moet gebruik
- hoeveel van die ander medisynes u tesame met NEOLED moet gebruik, indien enige.
- op watter dae van u behandelingsiklus u elke medisyne moet neem.

***Hoe en wanneer om NEOLED te neem***

- sluk die kapsule heel, verkieslik met water.
- moenie die kapsule breek, oopmaak of kou nie. As poeier van 'n stukkende NEOLED-kapsule met die vel kontak maak, was die vel onmiddellik met seep en water.
- die kapsules kan met of sonder kos geneem word.
- u moet NEOLED op ongeveer dieselfde tyd op die geskeduleerde dae neem.

***As u meer NEOLED gebruik as wat u moet***

In die geval van oordosering, raadpleeg u dokter of apteker. As nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

***As u vergeet om NEOLED te gebruik***

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

***As u ophou om NEOLED te gebruik***

Moenie ophou om NEOLED te gebruik of u dosis verander sonder om eers met u dokter te praat nie. U dokter sal besluit op die duur van die behandeling.

#### 4. Moontlike newe-effekte

NEOLED kan newe-effekte hê.

Nie alle newe-effekte wat vir NEOLED aangemeld is word in hierdie voubiljet ingesluit nie. As u algemene gesondheid versleg of u ervaar enige ongewenste gevolge terwyl u NEOLED gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Staak gebruik van NEOLED en vertel u dokter onmiddellik as enige van die volgende gebeur of gaan na die ongevalle afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik maak om te sluk of asem te haal,
- uitslag of jeuking,
- floute (duiseligheid).
- ernstige allergiese reaksie wat as 'n uitslag in een area kan begin maar versprei met uitgebreide verlies van vel oor die hele liggaam (Stevens-Johnson sindroom en/of toksiese epidermale nekrolise)

Hierdie is almal baie ernstige newe-effekte. As u dit het, kan u 'n ernstige reaksie vir NEOLED hê. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal as u enige van die volgende opmerk:

- koors, koue rillings, seerkeel, hoes, mondsere of enige ander simptome van infeksie, insluitend van die bloedstroom (sepsis)
- bloeding of kneusing in die afwesigheid van besering
- borspyn, wat na die arms, nek, kakebeen, rug of maag versprei, sweterige gevoel en asemnood, naar gevoel of braking, wat simptome van 'n hartaanval (miokardiale infarsie) kan wees
- beenpyn (wat simptome van trombose kan wees), borspyn of kortasem (wat simptome van bloedklonte in die longe, wat pulmonale embolisme genoem word, kan wees)
- wydverspreide uitslag, hoë liggaamstemperatuur, verhoogde lewerensieme, bloedafwykings (eosinofilie), vergrootte limfkliere en ander organe se betrokkenheid (Geneesmiddelreaksie met eosinofilie en sistemiese simptome, wat ook as DRESS bekend staan, of geneesmiddel-hipersensitiwiteit-sindroom).

Hierdie is almal ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter as u enige van die volgende opmerk:

##### *Gereeld*

- koors en griepagtige simptome, loopneus, seerkeel, seer spiere, hoofpyn, oorpyn en koue rillings
- hardlywigheid, diarree, naarheid, braking
- tandpyn
- droë mond, maagpyn, slegte spysvertering
- spierkrampe, swak spiere, spierpyn, pyn van die bene, gewrigspyne, rugpyn, pyn in die ledemate, moegheid, koors, algemene swelling van die arms en bene
- gevoelloosheid, naalde-en-spelde of brandsensasie van die vel, pyne in die hande of voete, duiseligheid, bewing, veranderinge in smaak
- beroerte
- neusbloeding, kortasem, infeksie van die boonste asemhalingskanaal
- infeksies van enige aard
- infeksie van die long en die boonste asemhalingskanaal, sinus infeksie
- droë vel, oormatige sweet

- 'n afname in die aantal rooibloedselle wat bloedarmoede kan veroorsaak wat tot moegheid en swakheid kan lei
- onderaktiewe skildklier
- verminderde eetlus
- toename van u bloedsuikervlak (diabetes)
- lae vlakke van kalium en/of natrium in die bloed
- lae vlakke van kalsium, fosfaat of magnesium in die bloed
- ontwatering
- 'n oormaat van yster in die liggaam
- versteurde visie
- vertroebeling in u oog (katarak)
- nierversaking
- lae- of hoë bloeddruk
- 'n soliede swelsel of gestolde bloed in die weefsels
- depressie, veranderde gemoedstoestand
- 'n ongereelde, vinnige hartklop wat simptome soos hartkloppings, moegheid, en kortasem kan veroorsaak
- bloedkankers
- verhoging in lewertoets-uitslae
- afname in gewig
- val

#### *Minder gereeld*

- Hipersensitiwiteit

#### *Onbekende gereeldheid*

- virale infeksies, insluitend herpes zoster (ook bekend as 'gordelroos', 'n virale siekte wat 'n pynlike veluitslag met blase veroorsaak) en herhaling van hepatitis B infeksie (wat vergeling van die vel en oë, donkerbruin urine, maagpyn aan die regterkant, koors en naar gevoel of siek gevoel kan veroorsaak).
- potensiele lewensbedreigende bloedversteuring
- verwerping van soliede orgaanplanting (soos nier, hart)
- hyg, kortasem of droë hoes, wat simptome kan wees van inflammasie van die weefsels in die longe
- skielike, of matige maar verergerende pyn in die bokant van die maag en/of rug, wat vir 'n paar dae voortduur, moontlik vergesel deur naarheid, braking, koors en vinnige pols – hierdie simptome mag as gevolg van inflammasie van die pankreas wees.
- afbreuk van die wand van die maag of derms. Dit mag to baie ernstige infeksie lei. Vertel u dokter as u ernstige maagpyn, koors, naarheid, braking, bloed in u stoelgang, of verandering in stoelgang-gewoontes ervaar.
- geel pigmentasie van die vel, slymvliese of oë (geelsug), bleekgekleurde stoelgange, donker urine, jeuking van vel, uitslag, pyn of swelling van die maag – hierdie kan simptome van skade aan die lewer wees (hepatiese versteuring).
- 'n toestand wat die vel aantast wat deur inflammasie van die klein bloedvate veroorsaak word, tesame met pyn van die gewigte en koors.
- Tumor lysis sindroom – metaboliese komplikasies wat tydens behandeling van kanker of somtyds selfs sonder behandeling kan voorkom. Hierdie komplikasies word veroorsaak deur die afbreuk produkte van sterwende kankerselle en mag die volgende insluit; veranderings aan bloedchemie – hoë kalium, fosfor, uriensuur, en lae kalsium wat gevolglik lei tot veranderinge in nierfunksie, hartklop, stuipe, en somtyds dood.



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

### **Aanmelding van newe-effekte**

As u newe-effekte ervaar, praat met u dokter, apteker of verpleegster. U kan newe-effekte ook by SAHPRA aanmeld via die “**6.04 Adverse Drug Reaction Reporting Form**”, aanlyn gevind onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld kan u help met meer inligting oor die veiligheid van NEOLED.

## **5. Hoe om NEOLED te bêre**

BÊRE ALLE MEDISYNE BUIITE BEREIK VAN KINDERS.

Bêre teen of laer as 25 °C.

Hou die kapsule in die stulpverpakking in die buitenste kartondosie totdat dit gebruik moet word.

Moenie na die vervaldatum soos op die etiket/dosie/bottel aangedui gebruik nie.

Gee alle ongebruikte medisyne aan u apteker terug.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) afspoel nie.

## **6. Inhoud van pak en ander inligting**

### **Wat NEOLED bevat**

Die aktiewe bestanddeel is lenalidomied.

Die ander bestanddele is sellulose; mikrokristallyn, kroskarmellose natrium, laktose, magnesiumstearaat.

*Kapsule doppie*

NEOLED 2,5 & 10 & 20 mg

Gelatien, Indigotien – FD&C Blou #2 (E132), titaandioksied (E171), geel ysteroksied (E172).

NEOLED 5 & 25 mg

Gelatien, titaandioksied (E171).

NEOLED 7,5 mg

Gelatien, titaandioksied (E171), geel ysteroksied (E172).

*Kapsule ink:* Ysteroksied swart (E172), kaliumhidroksied (E525), propileenglikol (E1520), skellak (E904), sterk ammoniumoplossing (E527).

NEOLED 15 mg

Gelatien, titaandioksied (E171), Indigotien – FD&C Blou #2 (E132)

### **Hoe NEOLED yk en inhoud van die pak**

*NEOLED 2, 5 mg (harde kapsules)*

’n Ondeursigtige wit harde gelatienkapsule, met ’n groen doppie met “L9NL” en “2.5” radiaal op die kapsule gedruk. Kapsule grootte: 4

*NEOLED 5 mg (harde kapsules)*

’n Ondeursigtige wit harde gelatien kapsule met ondeursigtige wit doppie met “L9NL” en “5” radiaal op die kapsule gedruk. Kapsule grootte: 2

*NEOLED 7,5 mg (harde kapsules)*

’n Ondeursigtige wit harde gelatien kapsule met ondeursigtige geel doppie met “L9NL” en “7.5” radiaal op die kapsule gedruk. Kapsule grootte: 2

*NEOLED 10 mg (harde kapsules)*

’n Ondeursigtige geel gelatien kapsule met ondeursigtige groen doppie met “L9NL” en “10” radiaal op die kapsule gedruk. Kapsule grootte: 0

*NEOLED 15 mg (harde kapsules)*

’n Ondeursigtige wit gelatien kapsule met ondeursigtige blou doppie met “L9NL” en “15” radiaal op die kapsule gedruk. Kapsule grootte: 0

*NEOLED 20 mg (harde kapsules)*

'n Ondeursigtige blou gelatien kapsule met ondeursigtige groen doppie met "L9NL" en "20" radiaal op die kapsule gedruk. Kapsule grootte: 0

*NEOLED 25 mg (harde kapsules)*

'n Ondeursigtige wit gelatien kapsule met ondeursigtige wit doppie met "L9NL" en "25" radiaal op die kapsule gedruk. Kapsule grootte: 0

Die kapsules is verpak in 'n oPA/Al/PVC/Al stulpverpakking (verpak in kartondosies).

**Houer van Registrasiesertifikaat**

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**Registrasie/ Aansoeknommer**

Neoled 2,5 mg 54/32/0540

Neoled 5 mg 54/32/0541

Neoled 7,5 mg 54/32/0542

Neoled 10 mg 54/32/0543

Neoled 15 mg 54/32/0544

Neoled 20 mg 54/32/0545

Neoled 25 mg 54/32/0546

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