PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

NAUSETRON 4 mg INJECTION

NAUSETRON 8 mg INJECTION

The active substance is ondansetron hydrochloride dihydrate; each 1 mL of solution contains 2 mg ondansetron.

- **Each 2 mL ampoule NAUSETRON 4 mg INJECTION contains 4 mg ondansetron**
- **Each 4 mL ampoule NAUSETRON 8 mg INJECTION contains 8 mg ondansetron**

Sugar free

Read all of this leaflet carefully before you are given NAUSETRON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider

What is in this leaflet

1. What NAUSETRON is and what it is used for

NAUSETRON contains the active ingredient ondansetron, which belongs to a group of medicines called anti-emetics (anti-nausea medicines).

Certain medicines may cause nausea and vomiting. Ondansetron blocks the effect of these medicines in the brain, which helps you not to feel sick (nauseous) or to be sick (vomit).

NAUSETRON may be used to treat nausea and vomiting caused by:

- Medicines for cancer (chemotherapy)
- Radiotherapy for cancer
- Having an operation.

2. What you need to know before you are given NAUSETRON

You should not be given NAUSETRON

- If you are hypersensitive (allergic) to ondansetron, or to any of the ingredients of **NAUSETRON**
- If you are pregnant or breastfeeding your baby (see "**Pregnancy, breastfeeding and fertility**")
- If you are being treated with apomorphine (a medicine used for Parkinson's disease)
- If you have a genetic heart condition that causes irregular heartbeats e.g. long QT syndrome
- If you are taking or receiving other medicines that cause long QT syndrome.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- If your liver does not work well – you may need a lower dose of **NAUSETRON**
- If you previously had an allergic reaction to other similar medicines (e.g. granisetron or dolasetron). It is possible that you may also be allergic to **NAUSETRON** and your doctor may want to prescribe another medicine
- If you have a blockage in your gut or suffer from severe constipation, as **NAUSETRON** can affect the motility of the lower gut (i.e. slow movement of the gut which may worsen the constipation)
- If you have heart problems with irregular heartbeats (dysrhythmia) or other heart disorders, e.g. congestive heart failure which causes shortness of breath and swollen ankles
- If you use or take medicines for dysrhythmia, or beta-blockers, at the same time
- If you have heart problems including abnormal heart rhythm (see "**Possible side effects**")
- If you know that you have an imbalance of salts (electrolytes) which regulate important functions in your body or are on a salt restricted diet
- If your child is younger than 2 years of age, as he/she should not receive **NAUSETRON** after an operation
- If your child is less than 4 years of age, as he/she should not receive **NAUSETRON** for nausea and vomiting caused by cancer treatment.

If you are having blood or urine tests done, always tell the laboratory that you are being treated with **NAUSETRON**.

Other medicines and NAUSETRON

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

If you are taking medicines on a regular basis, using **NAUSETRON** at the same time may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Inform your doctor if you are taking or receiving any of the following medicines:

- Apomorphine (used to treat Parkinson's disease) (see "**You should not be given NAUSETRON**")
- Serotonergic medicines (medicines of the SSRI or SNRI types, used in the treatment of depression)
- Medicines that may cause heart damage (e.g. anthracyclines and trastuzumab used for cancer treatment)
- Any heart medications that control the rhythm of the heart (such as amiodarone)
- Beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines (such as atenolol or timolol)
- Tramadol (medicine used for severe pain)
- Antibiotics and antifungal medicines (such as erythromycin or ketoconazole)
- Carbamazepine or phenytoin (medicines to control fits/seizures)
- Rifampicin (medicine used to treat tuberculosis (TB))
- Other medicines that cause long QT syndrome.

Receiving **NAUSETRON** while taking these medicines may cause undesirable interactions. Your doctor will decide whether to lower the dose of your medicine or to prescribe another medicine.

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 this medicine.

You should not be given **NAUSETRON** if you are pregnant or think you are pregnant. Ondansetron passes into breastmilk. Therefore, you should not breastfeed your baby if you are using **NAUSETRON** (see "**You should not be given NAUSETRON**").

Driving and using machines

NAUSETRON may make you dizzy or drowsy or cause blurred vision.

If this happens, do not drive or operate any tools or machines until you know how **NAUSETRON** could interfere with your ability to drive safely.

NAUSETRON contains sodium

NAUSETRON contains 3,6 mg of sodium in each mL of solution for injection. Please tell your doctor if you are on a sodium (salt) restricted diet.

3. How NAUSETRON is administered

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

You will not be expected to inject yourself with **NAUSETRON**.

NAUSETRON will be administered to you by a doctor or healthcare professional in a hospital setting, clinic or doctor's rooms.

NAUSETRON is slowly injected into the muscle, or the vein, or dripped into the vein as an intravenous infusion.

Dosage:

Adults

Your doctor will decide on the correct dose of **NAUSETRON** for you.

The dose varies depending on your medical treatment (chemotherapy or surgery), on your liver function, and on whether it is given to you by injection or infusion.

Children

NAUSETRON should not be given to children younger than 2 years of age for nausea and vomiting after operations, or less than 4 years of age after cancer treatment.

Your child's doctor will determine the correct dose for your child.

Dosage adjustment:

Liver impairment

If you have liver problems, your doctor will adjust your dose to a maximum daily dose of 8 mg **NAUSETRON**.

Method and route of administration:

NAUSETRON is injected into a muscle or a vein, or dripped into a vein as an intravenous infusion.

In the unlikely event that the needle comes out or becomes loose while **NAUSETRON** is being given, or if the solution spreads into the tissue outside the vein, immediately tell your doctor or healthcare professional (see "**Possible side effects**).

Frequency of administration

Your doctor will decide how often you should receive **NAUSETRON**.

Duration of treatment

Your doctor will decide on the duration of **NAUSETRON** therapy for you.

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

If you are given more NAUSETRON than you should be given

Since a healthcare provider will administer **NAUSETRON**, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

Signs of overdose may be severe constipation, problems with vision, feeling faint and an increased occurrence of side effects (see "**Possible side effects**).

If you have any questions about your treatment, ask your doctor or pharmacist.

If you missed a dose of NAUSETRON

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

Since a healthcare provider will administer **NAUSETRON**, it is unlikely that the dose will be missed.

4. Possible side effects

NAUSETRON can have side effects.

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

If any of the following happens, stop receiving **NAUSETRON** and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, wheezing. You may have a severe allergic reaction.
- Skin rash, hives and/or itching. You may have a severe allergic reaction.
- Blindness. This is temporary.
- Shock.

These are all very serious side effects. Some of these may indicate that you are having a severe allergic reaction to **NAUSETRON**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Uneven heartbeat, chest pain, fits
- Heart problems including abnormal heart rhythm and lack of blood flow to the heart.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Sensation of warmth or flushing
- Constipation, slow movement of food through the large bowel
- Pain, redness or burning at site of injection (see "**Method and route of administration**" above, under "**How NAUSETRON is administered**").

Less frequent side effects:

- Depression (a state of feeling sad)
- Chest pain, abnormal or irregular heartbeat
- Dizziness, light-headedness (you may have low blood pressure)
- Seizures (fits), uncontrollable and repetitive movements, eye-rolling
- Blurred vision
- Hiccups
- Increases in liver function tests, particularly when you are also treated with cisplatin (for cancer). Always tell the laboratory if you are having blood tests, that you are being treated with **NAUSETRON**.

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 **NAUSETRON**.

5. How to store NAUSETRON

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from light; keep the ampoules in the outer container.

NAUSETRON is stored in the hospital/clinic dispensary.

The doctor or healthcare professional will first inspect the NAUSETRON solution and will not use it if any particles are seen.

The ampoules are for single use only. Any unused solution should be discarded.

Do not use **NAUSETRON** after the expiry date which is stated on the carton and the ampoule after the words "Do not use after" or "Exp". The first two numbers indicate the month; the last numbers indicate the year. The expiry date refers to the last day of the month.

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 NAUSETRON contains

The active substance is ondansetron hydrochloride dihydrate; each 1 mL of solution contains 2 mg ondansetron.

- Each 2 mL ampoule **NAUSETRON 4 mg INJECTION** contains 4 mg ondansetron
- Each 4 mL ampoule **NAUSETRON 8 mg INJECTION** contains 8 mg ondansetron

The other ingredients are: citric acid, sodium citrate, sodium chloride and water for injection.

What NAUSETRON looks like and contents of the pack

NAUSETRON 4 mg INJECTION: clear, colourless solution, free of visible particulate matter.

NAUSETRON 8 mg INJECTION: clear, colourless solution, free of visible particulate matter.

NAUSETRON 4 mg INJECTION: Carton containing 5 clear glass ampoules.

NAUSETRON 8 mg INJECTION: Carton containing 5 clear glass ampoules.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road

Aeroton

Johannesburg

2013

Tel: +27 11 494 8000

This leaflet was last revised in

Date of registration: 20 June 2005

Date amended: 31 October 2024

Registration number

NAUSETRON 4 mg INJECTION: A39/5.10/0462

NAUSETRON 8 mg INJECTION: A39/5.10/0463

PIL 31 October 2024

PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS: **S4**

NAUSETRON 4 mg INJECTION

NAUSETRON 8 mg INJECTION

Die aktiewe bestanddeel is ondansetron hidrochlorieddihidraat; elke 1 mL oplossing bevat 2 mg ondansetron.

- **Elke 2 mL ampul NAUSETRON 4 mg INJECTION bevat 4 mg ondansetron**
- **Elke 4 mL ampul NAUSETRON 8 mg INJECTION bevat 8 mg ondansetron**

Suikervry

Lees die hele voubiljet noukeurig deur voordat NAUSETRON aan u gegee word

- Bewaar hierdie voubiljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgkundige

Wat in hierdie voubiljet is

1. Wat NAUSETRON is en waarvoor dit gebruik word

NAUSETRON bevat die aktiewe bestanddeel ondansetron, wat behoort aan 'n groep medisyne genaamd anti-emetika (medisyne teen naarheid).

Sekere medisyne kan naarheid en braking veroorsaak. Ondansetron blokkeer die effek van hierdie medisyne in die brein, wat u help om nie siek (naar) te voel of te braak (opgooi) nie.

NAUSETRON kan gebruik word om naarheid en braking te behandel wat veroorsaak word deur:

- Medisyne vir kanker (chemoterapie)
- Radioterapie vir kanker
- 'n Operasie ondergaan.

2. Wat u behoort te weet voordat u NAUSETRON ontvang

NAUSETRON moet nie aan u gegee word nie:

- Indien u hipersensitief (allergies) is vir ondansetron, of vir enige van die bestanddele van **NAUSETRON**
- Indien u swanger is of u baba borsvoed (sien "**Swangerskap, borsvoeding en vrugbaarheid**")
- Indien u met apomorfien behandel word ('n medisyne wat vir Parkinson se siekte gebruik word)

- Indien u 'n genetiese harttoestand het wat onreëlmatige hartklop veroorsaak bv. lang QT-sindroom
- Indien u ander medisyne neem of ontvang wat lang QT-sindroom veroorsaak.

Waarskuwings en voorsorgmaatreëls

Lig u dokter of gesondheidsorg kundige in voordat u die inspuiting gegee word:

- Indien u lewer nie goed werk nie – u mag dalk 'n laer dosis **NAUSETRON** benodig
- Indien u voorheen 'n allergiese reaksie op ander soortgelyke medisyne gehad het (bv. granisetron of dolasetron). Dit is moontlik dat u ook allergies is vir **NAUSETRON** en u dokter sal dalk 'n ander medisyne wil voorskryf
- Indien u 'n blokkasie in u ingewande het of aan erge hardlywigheid ly, aangesien **NAUSETRON** die beweeglikheid van die onderste ingewande kan beïnvloed (m.a.w. stadige beweging van die derm wat die hardlywigheid kan vererger)
- Indien u hartprobleme het met onreëlmatige hartklop (disritmie) of ander hartafwykings, bv. kongestiewe hartversaking wat kortasem en geswelde enkels veroorsaak
- Indien u medisyne vir disritmie, of betablokkers, terselfdertyd gebruik of neem
- Indien u hartprobleme het, insluitend abnormale hartritmes (sien “**Moontlike newe-effekte**”)
- Indien u weet dat u 'n wanbalans van soute (elektroliete) het wat belangrike funksies in u liggaam reguleer, of op 'n soutbeperkte dieet is
- Indien u kind jonger as 2 jaar oud is, aangesien hy/sy nie **NAUSETRON** na 'n operasie behoort te ontvang nie
- Indien u kind jonger as 4 jaar oud is, aangesien hy/sy nie **NAUSETRON** moet ontvang vir naarheid en braking wat deur kankerbehandeling veroorsaak word nie.

Indien u bloed- of urinetoetse laat doen, lig altyd die laboratorium in dat u met **NAUSETRON** behandel word.

Ander medisyne en NAUSETRON

Lig altyd u gesondheidsorg kundige in indien u enige ander medisyne gebruik.
Dit sluit alle komplementêre of tradisionele medisyne in).

Indien u gereeld medisyne gebruik, kan die gebruik van **NAUSETRON** op dieselfde tydstip ongewenste interaksies veroorsaak. Raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Lig u dokter in indien u enige van die volgende medisyne neem of ontvang:

- Apomorfien (word gebruik om Parkinson se siekte te behandel) (sien "**U moet nie NAUSETRON gegee word nie**")
- Serotonergiese medisyne (medisyne van die SSHI- of SNHI-tipes, gebruik in die behandeling van depressie)
- Medisyne wat hartskade kan veroorsaak (bv. antrasikliene en trastuzumab wat vir kankerbehandeling gebruik word)
- Enige hartmedikasie wat die ritme van die hart beheer (soos amiodaroon)
- Betablokker-middels wat gebruik word om sekere hart- of oogprobleme, angs te behandel of migraine te voorkom (soos atenolol of timolol)
- Tramadol (medisyne wat gebruik word vir erge pyn)
- Antibiotika en medisyne teen swamme (soos eritromisien of ketokonasool)
- Karbamasepien of fenitoïen (medisyne om aanvalle/stuipe te beheer)
- Rifampisien (medisyne wat gebruik word om tuberkulose (TB) te behandel)

- Ander medisyne wat lang QT-sindroom veroorsaak.

Gebruik van **NAUSETRON** terwyl hierdie medisyne geneem word, kan ongewenste interaksies veroorsaak. U dokter sal besluit of u die dosis van u medisyne moet verlaag of 'n ander medisyne voorgeskryf moet word.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of u baba borsvoed, dink dat u dalk swanger is of beplan om ‘n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat u hierdie medisyne neem.

U moet nie **NAUSETRON** gegee word as u swanger is of dink u dalk swanger is nie.
Ondansetron word uitgeskei in borsmelk. Daarom moet u nie u baba borsvoed as u **NAUSETRON** gebruik nie (sien “**U moet nie NAUSETRON gegee word nie**”).

Bestuur van ‘n voertuig en gebruik van masjinerie

NAUSETRON kan u duiselig of lomerig maak of versteurde visie veroorsaak.
Indien dit gebeur, moenie ‘n voertuig bestuur of enige gereedskap of masjiene hanteer totdat u weet hoe **NAUSETRON** u vermoë om veilig te bestuur kan inmeng nie.

NAUSETRON bevat natrium

NAUSETRON bevat 3,6 mg natrium in elke mL oplossing vir inspuiting. Lig asseblief u dokter in as u op 'n natrium (sout) beperkte dieet is.

3. Hoe NAUSETRON toegedien word

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

Daar sal nie van u verwag word om uself met **NAUSETRON** in te spuit nie.

NAUSETRON sal deur 'n dokter of gesondheidsorg kundige in 'n hospitaal-opset, kliniek of dokter se spreekkamer aan u toegedien word.

NAUSETRON word stadig in die spier, of die aar ingespuit, of as 'n binneaarse infusie in die aar gedrup.

Dosering:

Volwassenes

U dokter sal besluit oor die korrekte dosis **NAUSETRON** vir u.

Die dosis wissel na gelang van u mediese behandeling (chemoterapie of chirurgie), van u lewerfunksie, en of dit aan u gegee word deur inspuiting of infusie.

Kinders

NAUSETRON moet nie aan kinders jonger as 2 jaar gegee word vir naarheid en braking na operasies, of jonger as 4 jaar na kankerbehandeling nie.

U kind se dokter sal die korrekte dosis vir u kind bepaal.

Dosis aanpassing:

Lewerinkorting

Indien u lewerprobleme het, sal u dokter u dosis aanpas tot 'n maksimum daaglikse dosis van 8 mg **NAUSETRON**.

Metode en roete van toediening:

NAUSETRON word in 'n spier of 'n aar ingespuit, of as 'n binneaarse infusie in 'n aar gedrup.

In die onwaarskynlike geval dat die naald uitkom of los raak terwyl **NAUSETRON** toegedien word, of as die oplossing in die weefsel buite die aar versprei, lig dadelik u dokter of gesondheidsorg kundige in (sien "**Moontlike newe-effekte"**).

Frekwensie van toediening

U dokter sal besluit hoe gereeld u **NAUSETRON** moet ontvang.

Duur van behandeling

U dokter sal besluit oor die duur van **NAUSETRON**-terapie wat u ontvang.

Indien u die indruk kry dat die effek van **NAUSETRON** te sterk of te swak vir u is, lig u dokter of apteker in.

Indien u meer NAUSETRON gegee word as wat u moet kry

Aangesien 'n gesondheidsorg kundige **NAUSETRON** sal toedien, sal hy/sy die dosis beheer.

Nieteenstaande, in die geval van 'n oordosis sal u dokter die oordosis hanteer.

Tekens van oordosis kan erge hardlywigheid, probleme met visie, flou voel en 'n verhoogde voorkoms van newe-effekte wees (sien "**Moontlike newe-effekte"**).

Indien u enige vrae oor u behandeling het, raadpleeg u dokter of apteker.

Indien u 'n dosis NAUSETRON gemis het

Moenie 'n dubbele dosis ontvang om vergete individuele dosisse in te haal nie.

Aangesien 'n gesondheidsorg kundige **NAUSETRON** sal toedien, is dit onwaarskynlik dat 'n dosis gemis sal word.

4. Moontlike newe-effekte

NAUSETRON kan newe-effekte hê.

Nie alle newe-effekte wat vir **NAUSETRON** aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige nadelige effekte ervaar terwyl u **NAUSETRON** ontvang, raadpleeg u gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **NAUSETRON** en lig u dokter dadelik in:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal, hyg. U kan 'n ernstige allergiese reaksie hê.
- Veluitslag, galbulte en/of jeuk. U kan 'n ernstige allergiese reaksie hê.
- Blindheid. Dit is tydelik.
- Skok.

Dit is alles baie ernstige newe-effekte. Sommige hiervan kan aandui dat u 'n ernstige allergiese reaksie op **NAUSETRON** het. U benodig dalk dringende mediese aandag of hospitalisasie.

Lig u dokter in indien u enige van die volgende opmerk:

- Ongelyke hartklop, borspyn, stuipaanvalle
- Hartprobleme insluitende abnormale hartritme en tekort aan bloedvloei na die hart.

Hierdie is alles ernstige newe-effekte. U benodig dalk dringende mediese hulp.

Lig u dokter in indien u enige van die volgende opmerk:

Algemene newe-effekte:

- Hoofpyn
- Gevoel van warmte of blosing
- Hardlywigheid, stadige beweging van kos deur die dikderm
- Pyn, rooiheid of brand op die plek van inspuiting (sien "**Metode en roete van toediening**" hierbo, onder "**Hoe NAUSETRON toegedien word")**.

Minder algemene newe-effekte:

- Depressie ('n toestand van hartseer)
- Borspyn, abnormale of onreëlmatige hartklop
- Duiseligheid, lighoofdigheid (u kan lae bloeddruk hê)
- Stuipaanvalle (stuipe), onbeheerbare en herhalende bewegings, rol van die oog
- Versteurde visie
- Hik
- Toenames in lewerfunksietoetse, veral wanneer u ook met sisplatien (vir kanker) behandel word. Lig altyd die laboratorium in, indien u bloedtoetse ondergaan, dat u met **NAUSETRON** behandel word.

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

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die vorm **"6.04 Adverse Drug**

Reaction Reporting Form", wat gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan u help om meer inligting oor die veiligheid van **NAUSETRON** te verskaf.

5. Hoe om NAUSETRON te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre teen of benede 30 °C. Beskerm teen lig; hou die ampule in die buitenste houer.

NAUSETRON word in die apteek van die hospitaal/kliniek gestoor.

Die dokter of gesondheidsorg kundige sal eers die **NAUSETRON**-oplossing inspekteer en sal dit nie gebruik as enige deeltjies gesien word nie.

Die ampules is slegs vir eenmalige gebruik. Enige ongebruikte oplossing moet weggegooi word.

Moet nie **NAUSETRON** gebruik ná die vervaldatum wat op die karton en die ampule na die woorde "Moenie gebruik na" of "Verval" nie. Die eerste twee syfers dui die maand aan; die laaste syfers dui die jaar aan. Die vervaldatum verwys na die laaste dag van die maand.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat NAUSETRON bevat

Die aktiewe bestanddeel is ondansetron hidrochlorieddihidraat; elke 1 mL oplossing bevat 2 mg ondansetron.

- Elke 2 mL ampul **NAUSETRON 4 mg INJECTION** bevat 4 mg ondansetron

- Elke 4 mL ampul **NAUSETRON 8 mg INJECTION** bevat 8 mg ondansetron

Die ander bestanddele is: sitroensuur, natriumsitraat, natriumchloried en water vir inspuiting.

Hoe NAUSETRON lyk en die inhoud van die verpakking

NAUSETRON 4 mg INJECTION: helder, kleurlose oplossing, vry van sigbare deeltjies.

NAUSETRON 8 mg INJECTION: helder, kleurlose oplossing, vry van sigbare deeltjies.

NAUSETRON 4 mg INJECTION: Kartonboksie wat 5 deurskynende glas ampulle bevat.

NAUSETRON 8 mg INJECTION: Kartonboksie wat 5 deurskynende glas ampulle bevat.

Houer van die Sertifikaat van Registrasie

Adcock Ingram Critical Care (Edms.) Bpk.

Sabaxweg 1

Aeroton

Johannesburg

2013

Tel: +27 11 494 8000

Hierdie voubiljet is mees onlangs hersien op

Datum van registrasie: 20 Junie 2005

Datum hersien: 31 Oktober 2024

Registrasienommer

NAUSETRON 4 mg INJECTION: A39/5.10/0462

NAUSETRON 8 mg INJECTION: A39/5.10/0463

PIL 31 October 2024