PROFESSIONAL INFORMATION

SCHEDULING STATUS S2

PROPRIETARY NAMES AND DOSAGE FORM
Nexiflux 20 gastro-resistant tablet

COMPOSITION
Active ingredient:
Each **Nexiflux 20** gastro-resistant tablet contains 20 mg esomeprazole (as esomeprazole magnesium dihydrate).

Other ingredients:
Crospovidone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, macrogol 6000, magnesium stearate, methacrylic acid–ethyl acrylate copolymer, microcrystalline cellulose, polysorbate, povidone, sodium stearyl fumarate, sugar spheres (consisting of maize starch and sucrose), talc, triethyl citrate, Opadry Pink (consisting of hypromellose, iron oxide red, iron oxide yellow, macrogol, titanium dioxide).

PHARMACOLOGICAL CLASSIFICATION
A 11.4.3 Medicines acting on gastrointestinal tract

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Esomeprazole is the S-isomer of omeprazole which reduces gastric acid secretion through specific inhibition of the acid pump in the parietal cell.
Esomeprazole is a prodrug and is converted to the active form in the acidic environment of the secretory canaliculi of the parietal cell, where it inhibits the enzyme H^+K^+-ATPase – the acid pump. This action is dose-dependent and results in the inhibition of both basal and stimulated acid secretion.

Effect on gastric acid secretion:
The onset of effect of esomeprazole, taken orally at a dose of 20 mg, occurs within one hour. After repeated daily doses of 20 mg esomeprazole the mean peak acid output after pentagastrin stimulation is decreased by 90 % when measured 6 – 7 hours after dosing on day 5.
After 5 days of oral dosing with 20 mg of esomeprazole, intragastric pH above 4 is maintained for a mean time of 13 hours over 24 hours in symptomatic gastro-oesophageal reflux disease (GORD) patients. For esomeprazole 20 mg, the proportion of patients maintaining an intragastric pH above 4 for at least 8, 12 and 16 hours respectively are about 76 %, 54 % and 24 %. Using AUC as a surrogate parameter for plasma concentration, a relationship between inhibition of acid secretion and exposure has been demonstrated.

Pharmacokinetic properties
Absorption and distribution
Esomeprazole is acid labile and is enteric-coated for oral administration. *In vivo* conversion to the R-isomer is negligible. Esomeprazole is well absorbed with peak plasma levels occurring approximately 1-2 hours after dose.
The absolute bioavailability is 89 % after repeated once-daily administration. The apparent volume of distribution at steady state in healthy subjects is approximately 0,22 ℓ/kg body mass. Esomeprazole is 97 % plasma protein bound.
Food intake both delays and decreases the absorption of esomeprazole although this has no significant influence on the effect of esomeprazole on intragastric acidity.

Metabolism and excretion
Esomeprazole is metabolised by the cytochrome P450 system (CYP), primarily by isoenzyme CYP2C19 which is responsible for the formation of the hydroxy- and desmethyl metabolites of esomeprazole. The remaining part is dependent on another specific isoform, CYP3A4, responsible for the formation of esomeprazole sulphone, the main metabolite in plasma.
Total plasma clearance is about 17 ℓ/h after a single dose and about 9 ℓ/h after repeated administration. The plasma elimination half-life is about 1,3 hours after repeated once-daily dosing. The area under the plasma concentration-time curve increases with repeated administration of esomeprazole. This increase is dose-dependent and results in a more than dose proportional increase in AUC after repeated administration. This time- and dose- dependency is due to a decrease of first pass metabolism and systemic clearance probably caused by an inhibition of the CYP2C19 enzyme by esomeprazole and/or its sulphone metabolite. Esomeprazole is completely eliminated from plasma between doses with no tendency for accumulation during once-daily administration.
The major metabolites of esomeprazole have no effect on gastric acid secretion. Almost 80 % of an oral dose of esomeprazole is excreted as metabolites in the urine, the remainder in the faeces. Less than 1 % of the parent compound is found in urine.

Special patient populations
Elderly patients
The metabolism of esomeprazole is not significantly changed in elderly persons (71-80 years of age).

Liver impairment
The metabolism of esomeprazole in patients with mild to moderate liver dysfunction may be impaired. The metabolic rate is decreased in patients with severe liver dysfunction resulting in a doubling of the area under the plasma concentration-time curve of esomeprazole. Therefore, a maximum of 20 mg should not be exceeded in patients with severe dysfunction. Esomeprazole or its major metabolites do not show any tendency to accumulate with once-daily dosing.

Renal impairment
No data are available on patients with decreased renal function. Since the kidney is responsible for the excretion of the metabolites of esomeprazole but not for the elimination of the parent compound, the metabolism of esomeprazole is not expected to be changed in patients with impaired renal function.
Following repeated dose administration of 20 mg esomeprazole, the total exposure (AUC) and the time to reach maximum plasma esomeprazole concentration (t_{max}) in 12 to 18 year-olds was similar to that in adults for both esomeprazole doses.

INDICATIONS
Nexiflux tablets are indicated for:
Nexiflux tablets are indicated for the temporary short-term relief of heartburn and hyperacidity (see **Dosage and Directions for use**)

CONTRAINDICATIONS
Known hypersensitivity to esomeprazole, substituted benzimidazoles or any other constituents of the formulation.
Co-administration of Nexiflux with atazanavir or nelvinavir (see **INTERACTIONS**).

WARNINGS AND SPECIAL PRECAUTIONS
- Nexiflux is not indicated for mild gastrointestinal complaints such as nervous dyspepsia.
- Before prescribing Nexiflux to patients with gastric ulcers, or in the presence of symptoms such as significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena, the possibility of malignancy should be considered, since Nexiflux may mask symptoms and delay diagnosis.
- Symptomatic response to Nexiflux therapy does not preclude the presence of gastric ulcer or malignancy or a malignant disease of the oesophagus. The administration of Nexiflux in this situation may delay diagnoses.
- Increased risk of subclinical acute or chronic interstitial nephritis associated with protein pump inhibitors (PPI's) leading to chronic renal inflammation and reduced renal function. The preferred term to describe the histological findings of tubular injury being "tubulointerstitial nephritis". Acute tubulointerstitial nephritis is characterised by an inflammatory reaction within the tubulointerstitial space of the kidney. Acute interstitial inflammatory reactions are associated with damage to the tubulointerstitium, leading to acute kidney injury. Tubulointerstitial nephritis may be medicine-related, infectious, systemic, autoimmune, genetic, and idiopathic with the most common cause being related to a medication or medicine exposure. The risk of tubulointerstitial nephritis leading to chronic inflammation and reduced renal function associated with the use of protein pump inhibitors such as Nexiflux, is a class effect.

Infections
Nexiflux may increase the risk of gastrointestinal infections, such as *Salmonella* and *Campylobacter*, because of its acid suppressive effects (see **SIDE EFFECTS**).
Clostridium difficile associated diarrhoea (CDAD), a severe debilitating diarrhoea that does not improve, may occur. Symptoms may include watery stools, abdominal pain, fever and patients may develop more serious intestinal conditions.
A diagnosis of CDAD should be considered in patients with diarrhoea that does not improve. Patients should be advised to seek immediate medical attention if they experience watery stools, abdominal pain and fever while taking Nexiflux.
The lowest dose for the shortest duration of therapy, appropriate for the condition being treated, should be used.

Fractures
Proton pump inhibitors, like Nexiflux , especially in prolonged use (>1 year) and in high doses, may increase the risk of fractures of the hip, wrist and spine (see **SIDE EFFECTS**). This is of special importance in the elderly or in the presence of other recognised risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Other effects of acid inhibition
During treatment with antisecretory medicines, serum gastrin increases in response to the decreased acid secretion. During long-term treatment with antisecretory medicines, gastric glandular cysts have been reported to occur at an increased frequency due to long-term acid inhibition (see **SIDE EFFECTS**).
Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance.)

Hypomagnesaemia
Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors (PPIs) like Nexiflux for at least three months, and in most cases for a year. Severe hypomagnesaemia can correlate with hypocalcaemia. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular dysrhythmia can occur but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI.
For patients expected to be on prolonged treatment or who take Nexiflux with digoxin or medicines that may cause hypomagnesaemia (e.g., diuretics), it could be considered to measure magnesium levels before starting PPI treatment and periodically during treatment.

Hepatic impairment
In patients with cirrhosis of the liver increases in esomeprazole bioavailability and elimination half-lives have been reported. For dosage adjustment in patients with hepatic impairment, refer to DOSAGE AND DIRECTIONS FOR USE.
Nexiflux should be used with caution in hepatic impairment.

Special precautions
Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance.

Effects on ability to drive and use machines
Nexiflux is not likely to affect the ability to drive or use machines. Some patients may experience blurred vision, dizziness or vertigo (see **SIDE EFFECTS**) and should not drive or handle machines if that is the case.

INTERACTIONS
Nexiflux is metabolised via the hepatic P450 cytochrome enzyme system, which may affect the metabolism of other medications metabolised by these enzymes when given concomitantly.

Effects of Nexiflux on the pharmacokinetics of other medicines:
Medicines with pH dependent absorption:
Nexiflux, by inhibiting gastric acid secretion, has the potential to affect the bioavailability of any medicine with pH dependant absorption, such as protease inhibitors and antifungal agents.
Protease inhibitors: Increased gastric pH during Nexiflux treatment may change the absorption of the protease inhibitors. Other possible interaction mechanisms are via inhibition of CYP2C19. Nexiflux should not be used concomitantly with nelfinavir (plasma levels are increased). Concomitant use with atazanavir is not recommended; decreased serum levels of atazanavir may result (see **CONTRAINDICATIONS**).
Triazole antifungal medications: The decreased intragastric acidity during treatment with Nexiflux might increase or decrease the absorption of medicines if the mechanism of absorption is influenced by gastric acidity. The absorption of ketoconazole and itraconazole can decrease during treatment with Nexiflux .
The plasma concentration of both esomeprazole, contained in Nexiflux, and voriconazole (a CYP2C19 substrate) may be increased and a reduced dose of Nexiflux is recommended, particularly in patients with severe hepatic impairment and if long-term treatment is indicated.

Dasatinib:
Nexiflux can reduce the absorption of dasatinib, as its absorption is pH dependant.

Medicines metabolised by CYP2C19:
Nexiflux inhibits CYP2C19, the major esomeprazole metabolising enzyme. Concomitant administration with medicines metabolised by CYP2C19, such as diazepam, imipramine, clomipramine, citalopram, phenytoin etc., may increase the plasma concentrations of these medicines and a dose reduction could be needed. The plasma concentrations of phenytoin should be monitored when treatment with Nexiflux is introduced or withdrawn.

Cisapride:
Concomitant administration of Nexiflux and cisapride increases the exposure to cisapride and prolongs its elimination half-life (t½). This interaction did not alter the influence of cisapride on cardiac electrophysiology.

Anticoagulants:
Clinically significant elevated INR has been reported with Nexiflux. Monitoring of INR serum levels is recommended and dosage reductions may be necessary when Nexiflux is given concomitantly with warfarin or other anticoagulants.

Clopidogrel:
Clopidogrel is metabolised by CYP2C19. Nexiflux may reduce its antiplatelet effect due to esomeprazole's competitive inhibition of CYP2C19. There is a possible increased risk of cardiovascular events when Nexiflux is used with clopidogrel. Concomitant use of Nexiflux and clopidogrel is therefore not advisable.

Digoxin:
There is a possible interaction of Nexiflux with digoxin and a 10 % increase in digoxin bioavailability may be expected.

Iron salts:
Nexiflux may decrease the absorption of orally-administered iron salts.

Nonsteroidal anti-inflammatory drugs (NSAIDs):
No clinically relevant side effects have been recorded between Nexiflux and naproxen (non-selective NSAID) or rofecoxib (COX-2 selective NSAID).

Methotrexate:
Nexiflux may elevate serum concentrations of methotrexate and may be associated with delayed plasma elimination of methotrexate in patients given high-dose methotrexate therapy. In high-dose therapy with methotrexate a temporary withdrawal of Nexiflux may need to be considered.

Effects of other medicines on the pharmacokinetics of Nexiflux:
Inhibitors of CYP3A4:
- Clarithromycin is a potent inhibitor of CYP3A4 and Nexiflux is also metabolised via CYP3A4. Concomitant administration of Nexiflux and clarithromycin increases plasma levels of esomeprazole and 14-hydroxyclarithromycin. Dose adjustment of Nexiflux is not required.
- No clinical relevant interactions occur with amoxicillin.

Inducers of CYP2C19 or CYP3A4:
Medicines known to induce CYP2C19 or CYP3A4 or both (such as rifampicin and St. John's wort) may lead to decreased esomeprazole serum levels by increasing the esomeprazole metabolism.

Laboratory tests
NEXIFLUX may cause false-negative results in the urea breath test of *Helicobacter pylori* infection.

Investigations
Increased chromogranin A (CgA) levels may interfere with investigations for neuroendocrine tumours. To avoid this interference, Nexiflux treatment should be temporarily stopped for at least five days before CgA measurements.

PREGNANCY AND LACTATION
Safety during pregnancy and breast-feeding has not been determined.

DOSAGE AND DIRECTIONS FOR USE
Dosage for adults and adolescents from the age of 12 years:
Nexiflux may be taken once daily at a maximum daily dose of 20 mg (one Nexiflux tablet) for a maximum treatment period of 14 days.
The recommended once daily dosage of Nexiflux 20 mg tablets should preferably be taken 30 minutes before a meal.

Dosage for children below the age of 12 years
Nexiflux should not be used in children younger than 12 years since no data are available.

Impaired renal function
Dose adjustment is not required in patients with impaired renal function. Due to limited experience in patients with severe renal insufficiency, such patients should be treated with caution (see **Pharmacokinetic properties**).

Impaired hepatic function
Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a maximum dose of 20 mg Nexiflux should not be exceeded (see **Pharmacokinetic properties**).

Elderly patients (above 65 years)
Dose adjustment is not required in the elderly.

Directions for use:
The tablets should be swallowed whole with water. The tablets should not be chewed or crushed.
For patients who have difficulty in swallowing, the tablets may be dispersed in half a glass of non-carbonated water. No other liquids should be used as the enteric coat may be dissolved. The tablets should be stirred until they disintegrate and the liquid with the pellets should be drunk immediately. The empty glass should be rinsed with half a glass of water and swallowed. The pellets must not be chewed or crushed.
For patients who cannot swallow, the tablets can be dispersed in non-carbonated water and administered through a gastric tube. It is important that the appropriateness of the selected syringe and tube is carefully tested.

SIDE EFFECTS
Infections and infestations
Less frequent: Gastrointestinal oroesophagealcandidiasis, respiratory infection, sinusitis.
Frequency unknown: Pancreatitis.

Neoplasms benign and malignant (including cysts and polyps)
Frequency unknown: Gastric glandular cysts (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Blood and the lymphatic system disorders
Less frequent: Leukopenia, thrombocytopenia, agranulocytosis, pancytopenia.

Immune system disorders
Less frequent: Hypersensitivity reactions e.g. angioedema and anaphylactic reaction/shock.

Metabolism and nutrition disorders
Less frequent: Peripheral oedema, hyponatraemia.
Frequency unknown: Hypomagnesaemia (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Psychiatric disorders
Less frequent: Insomnia, agitation, confusion, somnolence, depression, aggression, hallucination.

Nervous system disorders
Frequent: Headache.
Less frequent: Dizziness, paraesthesia, somnolence, taste disturbance, fatigue.

Eye disorders
Less frequent: Blurred vision.

Ear and labyrinth disorders
Less frequent: Vertigo.

Respiratory, thoracic and mediastinal disorders
Less frequent: Bronchospasm.

Gastrointestinal disorders
Frequent: Abdominal pain,diarrhoea, flatulence, constipation,nausea/ vomiting, dyspepsia.
Less frequent: Dry mouth, stomatitis.
Frequency unknown: Microscopic colitis.

Hepatobiliary disorders
Less frequent: Increased liver enzymes, hepatitis with or without jaundice, hepatic failure, hepatic encephalopathy.

Skin and subcutaneous tissue disorders
Less frequent: Dermatitis, pruritus, rash, urticaria, alopecia; photosensitivity, bullous eruption.

Frequency unknown: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN).

Musculoskeletal, connective tissue and bone disorders
Less frequent: Arthralgia, myalgia, muscular weakness, fractures of the hip, wrist and spine (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Renal and urinary disorders
Less frequent: Interstitial nephritis.

Reproductive system and breast disorders
Less frequent: Gynaecomastia.

General disorders and administration site conditions
Less frequent: Malaise, increased sweating.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Symptoms of overdosage may include gastrointestinal symptoms and weakness.
No specific antidote is known. Nexiflux is extensively plasma protein bound and is therefore not readily dialysable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

IDENTIFICATION
Nexiflux 20: Light pink coated 6,55 x 13,6 mm, elliptically shaped, biconvex gastro- resistant tablet.

PRESENTATION
Nexiflux 20 and gastro-resistant tablets are packed in one of the following packaging materials, in packs containing 14 tablets:
- Blister strips consisting of a silver coloured plain aluminium foil and silver coloured cold forming blister aluminium foil (Alu/Alu blister) in an outer carton.
- Blister strips consisting of a silver coloured plain aluminium foil and clear colourless PVC/PVDC foil in an outer carton.

Not all pack sizes are necessarily marketed at any one time.

STORAGE INSTRUCTIONS
Store at or below 25 °C in a dry place in the original packaging. Keep blisters in the carton until required for use. Keep container tightly closed.

REGISTRATION NUMBERS
Nexiflux 20 mg: 48/11.4.3/0436

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:
Astral Pharma (Pty) Ltd
125 Meade Street
1st Floor Beacon Place
George
6529

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PATIENT INFORMATION LEAFLET
Nexiflux 20

SCHEDULING STATUS S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Nexiflux 20 gastro-resistant tablet

Read all of this leaflet carefully before you start taking Nexiflux.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Nexiflux 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.

1. WHAT NEXIFLUX CONTAINS
The active substance is esomeprazole.
Each **Nexiflux 20** tablet contains 20 mg esomeprazole (as esomeprazole magnesium dihydrate).
The other ingredients are listed below in alphabetical order, coating materials included.
Crospovidone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, macrogol 6000, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, microcrystalline cellulose, polysorbate, povidone, sodium stearyl fumarate, sugar spheres (consisting of maize starch and sucrose), talc, triethyl citrate, Opadry Pink (consisting of hypromellose, iron oxide red, iron oxide yellow, macrogol, titanium dioxide).

2. WHAT NEXIFLUX IS USED FOR
Nexiflux contains esomeprazole, which belongs to a group of medicines called proton pump inhibitors. Esomeprazole acts on the gastrointestinal tract and decreases the amount of acid that your stomach produces.
Nexiflux is used for the temporary, short-term relief of heartburn and increased acid (hyperacidity) of the stomach (see **How to take Nexiflux**).

3. BEFORE YOU TAKE NEXIFLUX
Do not take Nexiflux if you:
- are hypersensitive (allergic) to esomeprazole or other medicines called benzimidazoles, or any of the other ingredients of Nexiflux ;
- are taking medicines called atazanavir or nelfinavir (antiretroviral medicines used to treat human immunodeficiency virus (HIV)).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist or professional healthcare provider.

Take special care with Nexiflux
The presence of other medical problems may affect the use of Nexiflux. Nexiflux may hide symptoms of other diseases, therefore it is important to talk to your doctor, pharmacist or healthcare professional before taking Nexiflux and during the use of Nexiflux if you:
- vomit frequently, have stomach pain, indigestion or have lost a lot of weight without reason and have problems swallowing or if you pass dark stools (may contain blood);
- have osteoporosis (a bone disorder where you lose bone mass), as you may break your hip, wrist and spine more easily if you take Nexiflux for a long time;
- take digoxin (a heart medicine) or diuretics (water tablets), as you may develop a serious shortage of magnesium in your blood; and
- have serious liver problems, as your doctor may want to lower your dosage.

You should know that taking Nexiflux may mask the symptoms of gastric cancer, it is therefore important that you tell your doctor about any of the above symptoms, or other symptoms that you are concerned about.
Nexiflux suppresses the acid in your stomach. This may cause the number of *Clostridium difficile* bacteria (germs) present in your gut to increase greatly and to produce toxins (poisons) that affect your small and large bowels. Tell your doctor immediately if you get a fever as well as stomach pain and a very runny tummy with watery stools. Do not treat yourself to stop such loose bowel movements; speak to your doctor.
Taking Nexiflux for a long time, may cause cysts (a closed sac that contains fluid or semisolid material) in the glands of your stomach. Make sure that you keep to your regular follow-up appointments with your doctor while you take Nexiflux. He/she will tell you if you need any further diagnostic procedures.
Nexiflux can cause an increased risk of kidney disease leading to kidney failure. This is called tubulointerstitial nephritis and you may have increased urine output, blood in your urine or dark urine, changes in mental status, such as drowsiness or confusion, swelling of any area of your body.

Taking Nexiflux with food or drink
You should take Nexiflux on an empty stomach (at least 30 minutes before you eat). Only take Nexiflux with water (see **HOW TO TAKE NEXIFLUX**).

Pregnancy and breastfeeding
Nexiflux should not be used if you are pregnant or breastfeeding.
If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking Nexiflux.

Driving and using machinery
If Nexiflux causes you to become dizzy or have blurred vision, you should not drive or handle dangerous tools.

Important information about some of the ingredients of Nexiflux
Nexiflux 20 contains about 5,65 mg sugar (as sucrose), per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Nexiflux.

Taking other medicines with Nexiflux
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Also tell your doctor, pharmacist or other healthcare professional if you are using or receiving any of the following medicines:
- Atazanavir or nelfinavir (antiretroviral medicines used to treat HIV).
- Ketoconazole, itraconazole or voriconazole (medicines used to treat fungal infections such as thrush, ringworm).
- Diazepam, imipramine, clomipramine, citalopram and certain other medicines used for anxiety, depression or muscle spasms.
- Phenytoin (used in epilepsy). Your doctor may monitor your blood closely to check on the phenytoin levels when you start or stop taking Nexiflux.
- Cisapride (used for indigestion and heartburn).
- Digoxin (heart medicine).
- Iron supplements.
- NSAIDs (nonsteroidal anti-inflammatory drugs), used for pain and inflammation.
- Medicines to prevent blood clots such as warfarin and clopidogrel.
- Methotrexate (a medicine used for cancer or severe rheumatic conditions).
- Rifampicin (an antibiotic that may be used for tuberculosis (TB)).
- St John's wort (a herbal medicine that may be used for depression).

Nexiflux may prevent accurate diagnoses with some laboratory tests and procedures. Always tell your doctor or healthcare professional that you are taking Nexiflux.
If your doctor has prescribed amoxicillin and clarithromycin together with Nexiflux to treat ulcers caused by an infection with *Helicobacter pylori* (a germ), it is also very important that you tell your doctor about all other medicines that you are taking, including those that you have obtained yourself.
Before you begin using any new medicine (prescription or non-prescription), consult with your doctor, pharmacist or healthcare professional for advice.

4. HOW TO TAKE NEXIFLUX
Do not share medicines prescribed for you with any other person.
Always take Nexiflux exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Nexiflux is not intended for immediate relief of symptoms caused by heartburn.

- **Children below 12 years:**

Nexiflux is not recommended for children younger than 12 years of age.

- **Adults and children above 12 years:**

The usual dose is:
Take one Nexiflux 20 mg tablet once daily, for a maximum treatment period of 14 days.
Do not take more than 20 mg (One Nexiflux 20 m tablet) daily.

Elderly persons:
No special dosage is necessary if you are elderly (above 65 years).

How to take your tablets
Swallow your tablets whole, with a drink of water.
You can take Nexiflux at any time of the day, at least 30 minutes before a meal. Do not chew or crush the tablets, as the tablets consist of coated pellets which must not be damaged. These pellets are individually coated to ensure that the medicine is not broken down by the acid in your stomach.
- **If you have trouble swallowing the whole tablets:**

If you have difficulty in swallowing, the tablets can also be stirred in half a glass of non-carbonated water. Stir until the tablets disintegrate (the mixture will not be clear) and drink the water with the pellets immediately. No other liquids should be used, as the enteric coating on the pellets may dissolve. Rinse the glass with a little more water and finish it immediately. Do not chew these particles.
- **If you cannot swallow:**

The tablet can be mixed with some water and can be put into a syringe which is emptied into a gastric tube for direct administration into your stomach.
Your doctor will tell you how long your treatment with Nexiflux will last. Do not stop treatment early, as your symptoms may recur.
If you have the impression that Nexiflux is too strong or too weak, you should talk to your doctor or pharmacist.

If you take more Nexiflux than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.
Although signs of overdosage differ, you may possibly feel weak and have tummy problems (loose bowels and abdominal pain) and feel sick (nauseous).

If you forget to take a dose of Nexiflux
Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with Nexiflux is stopped
Talk to your doctor before you stop taking Nexiflux, as your symptoms may recur.

5. POSSIBLE SIDE EFFECTS
Nexiflux can have side effects.
Not all side effects reported for Nexiflux are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Nexiflux, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Nexiflux and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of the lips, face and eyes, abdominal pain, vomiting (being sick), difficulty breathing, wheezing or coughing (anaphylaxis) or swelling below the skin with red welts, burning, painful sometimes itchy skin areas, tight throat (angioedema).

These are all very serious side effects. If you have them, you may have a serious, potentially life-threatening allergic reaction to Nexiflux. 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 the following:
- Symptoms of the flu, including cough, fever and headache, followed by a painful rash that spreads and forms blisters. The blisters cause the affected skin to die and shed. The disease may leave the skin looking burned. These signs may be due to the Stevens-Johnson syndrome (a serious, sometimes fatal inflammatory disease).
- Yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice), or nausea, vomiting, loss of appetite, abdominal pain, dark urine, light coloured stools, tiredness (hepatitis with or without jaundice).
- Fever and infections – you may have leukopenia, agranulocytosis or pancytopenia (a severe reduction in number of white blood cells). Your doctor will order blood tests and treat you suitably.
- Blood in the urine, fever, nausea, swelling, increased or decreased urine output. You may have inflammation in the kidneys (interstitial nephritis). The inflammation can affect the kidneys' function, including their ability to filter waste. If you think you have this, call your doctor who will tell you what to do.
- Runny tummy with watery stools, fever and stomach pains. (See **Take special care with Nexiflux**).

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

Tell your doctor if you notice any of the following:
Frequently occurring side effects:
- Headache.
- Pain on the belly, diarrhoea, constipation, wind, nausea or vomiting (being sick).

Less frequently occurring side effects:
- Thrush (white spots due to yeast infection) with pain and inflammation (red tissue) in the mouth, gut or gullet. Your doctor may prescribe antifungal medicine if you have this disorder.
- Bruising easier and excessively, purple spots in skin, prolonged bleeding from cuts, spontaneous bleeding from nose or gums. You may have thrombocytopenia (a low blood platelet count). Your doctor will order blood tests and treat you suitably.
- Swelling of the feet and ankles.
- Increased sweating.
- Feeling weak, sick and having muscle cramps may be a sign that you have low blood sodium (hyponatraemia).
- Problems with sleeping (insomnia) or sleepiness, feeling agitated, confused or depressed, feeling aggressive; seeing, feeling or hearing things that are not there (hallucinations).
- Taste changes, dizziness, tingling of hands and/or feet – "pins and needles".
- Eyesight affected: blurred vision.
- Middle ear balance disorder.
- Breathing problems; feeling wheezy or short of breath.
- Dry mouth.
- Skin rash and skin sensitive for sunlight, lumpy rash (hives) and itching, hair loss.
- Joint pains or muscle pains; muscle or bone weakness which may possibly make it easier to break your wrist, spine and hip if you are injured.
- Enlarged breasts in men.
- Feeling unwell and lacking energy, sweating more than usually.

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

6. STORING AND DISPOSING OF NEXIFLUX
Store all medicines out of reach of children.
Store at or below 25 °C in a dry place in the original packaging. Keep blisters in the carton until required for use. Keep container tightly closed.
Do not store in a bathroom.
Do not use Nexiflux after the expiry date printed on the carton and on the blister. Return all unused or expired medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF NEXIFLUX
Nexiflux 20 gastro-resistant tablets are packed in one of the following packaging materials, in packs containing 14 tablets:
Blister strips consisting of a silver coloured plain aluminium foil and silver coloured cold forming blister aluminium foil (Alu/Alu blister) in an outer carton.
Blister strips consisting of a silver coloured plain aluminium foil and clear colourless PVC/PVDC foil in an outer carton.
Not all pack sizes are necessarily marketed at any one time.

8. IDENTIFICATION OF NEXIFLUX
Nexiflux 20: Light pink coated 6,55 x 13,6 mm, elliptically shaped, biconvex gastro-resistant tablet.

9. REGISTRATION NUMBERS
Nexiflux 20: 48/11.4.3/0436

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER
Astral Pharma (Pty) Ltd
125 Meade Street
1st Floor Beacon Place
George
6529

11. DATE OF PUBLICATION
13 April 2023

INLIGTINGSPAMFLET VIR DIE PASIËNT
Nexiflux 20

SKEDULERINGSTATUS S2

HANDELSNAAM, STERKTE EN DOSERINGSVORM

Nexiflux 20 maagsapbestande tablet

Lees die hele pamflet deeglik deur voordat Nexiflux begin neem.
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil deurlees.
- Indien jy nog vrae het, vra asseblief jou dokter of apteker.
- Nexiflux is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

1. WAT NEXIFLUX BEVAT
Die aktiewe bestanddeel is esomeprasool.
Elke **Nexiflux 20** tablet bevat 20mg esomeprasool (as esomeprasool magnesiumdihidraat). Bevat suiker.
Die ander bestanddele, asook die deklagie se bestanddele, is hieronder in alfabetiese volgorde gelys.
Gliserielmonostearaat, hidroksipropielsellulose, hipromellose, kruispovidoon, magnesiumstearaat, makrogol 6 000, metakrielsuuretielakrilaat-kopolimeer, mikrokristallyne sellulose, natriumstearielfumaraat, polisorbaat, povidoon, suikerkorrels (saamgestel uit mieliestysel en sukrose), talk, triëtielsitraat, Opadry-pienk (saamgestel uit hipromellose, rooi ysteroksied, geel ysteroksied, makrogol en titaandioksied).

2. WAARVOOR NEXIFLUX GEBRUIK WORD
Nexiflux bevat esomeprasool wat behoort aan 'n groep medisynes wat bekend staan as protonpompremmers. Esomeprasool werk op die maagdermkanaal en verminder die hoeveelheid suur wat jou maag vervaardig.
Nexiflux word gebruik vir die tydelike, korttermynverligting van sooibrand en verhoogde suur (hiperasiditeit) van die maag (sien **Hoe om Nexiflux te neem**).

3. VOORDAT JY NEXIFLUX NEEM
Moenie Nexiflux neem nie indien jy:
- hipersensitief (allergies) is vir esomeprasool of ander medisynes bekend as bensimidasole, of vir enige van die ander bestanddele van Nexiflux;
- jy tans medisyne neem soos atasanavir of nelfinavir (antiretrovirale medisyne, gebruik om die mens-immuungebreksvirus (MIV) te behandel).

Indien jy nie seker is of enige van die bogenoemde op jou van toespassing is nie, praat met jou dokter of apteker of professionele gesondheidsverskaffer daaroor.

Wees versigtig met Nexiflux
Die teenwoordigheid van ander mediese toestande kan die gebruik van Nexiflux beïnvloed. Nexiflux kan die simptome van ander siektes wegsteek. Dit is dus belangrik dat jy, voordat jy Nexiflux neem en ook terwyl jy dit neem, vir jou dokter, apteker of professionele gesondheidsorgkundige oor die volgende inlig:
- as jy dikwels opbring, maagpyn het of swak spysvertering, gewigsverlies sonder rede, probleme om te sluk of as jy donker stoelgange het (dit kan bloed bevat);
- as jy osteoporose het ('n beensiekte waar jy beenmassa verloor), want jy kan makliker jou heup, gewrigte en ruggraat breek as jy Nexiflux oor 'n lang tydperk neem;
- as jy digoksien neem ('n hartmedisyne), of diuretika ("water"- tablette), aangesien jy 'n ernstige tekort aan magnesium in jou bloed kan ontwikkel; en
- as jy ernstige lewerprobleme het, aangesien jou dokter jou dosis sal verlaag.

As jy Nexiflux neem moet jy weet dat die simptome van maagkanker kan onderdruk. Dit is dus belangrik dat jy jou dokter inlig oor enige van bogenoemde simptome, of ander simptome waaroor jy bekommerd is. Nexiflus onderdruk die suur in jou maag. Dit kan veroorsaak dat die aantal *Clostridium difficile* bakterieë (kieme) in jou derms baie kan vermeerder en ook toksiene (gifstowwe) kan afskei wat jou dun- en dikderm kan aantas. Laat weet dadelik jou dokter as jy koors en maagpyn kry met 'n loopmaag en waterige stoelgange. Moenie jouself behandel vir die loopmaag nie; gaan spreek jou dokter.
As jy Nexiflux oor 'n lang tydperk geneem het, kan die siste ('n geslote sakkie wat vloeistof of 'n halfvaste stof bevat) in die kliere van jou maag veroorsaak. As jy Nexiflux neem moet jy seker maak dat jy jou gereelde opvolgafsprake by jou dokter nakom. Hy/sy sal vir jou sê of jy bykomende diagnostiese prosedures benodig.
Nexiflux kan 'n verhoogde risiko vir niersiekte veroorsaak wat lei tot nierversaking. Dit word tubulo-interstisiële nefritis genoem en kan verhoogde urienproduksie, bloed in urine of donker urine veroorsaak, kan lei tot veranderinge in geestestoestand, soos slaperigheid of verwarring, of swelling van enige area van u liggaam tot gevolg hê.

Die gebruik van Nexiflux met kos of vloeistof
Neem Nexiflux op 'n leë maag (ten minste 30 minute voordat jy eet). Sluk Nexiflux slegs met water in (kyk **HOE OM NEXIFLUX TE NEEM**).

Swangerskap en borsvoeding
Nexiflux moet nie geneem word as jy swanger is of borsvoed nie.
Indien jy swanger is, of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige vir advies voordat jy Nexiflux neem.

Bestuur en gebruik van masjinerie
Indien Nexiflux veroorsaak dat jy duiselig voel, of jy sien nie so duidelik soos altyd nie, moet jy nie bestuur of gevaarlike gereedskap hanteer nie.

Belangrike inligting oor sommige van die bestanddele van Nexiflux
Nexiflux 20 bevat ongeveer 5,65 mg suiker (as sukrose) en per tablet. Indien jou dokter jou vroeër meegedeel het dat jy sekere suikers nie kan verdra nie, kontak jou dokter voordat jy Nexiflux neem.

Die gebruik van ander medisyne met Nexiflux
Lig altyd jou professionele gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).
Lig ook jou dokter, apteker of ander professionele gesondheidsorgkundige in as jy die volgende medisyne gebruik:
- Atasanavir of nelfinavir (antiretrovirale medisynes vir die behandeling van MIV).
- Ketokonasool, itrakonasool of vorikonasool (medisynes wat gebruik word om swaminfeksies soos sproei en omlope te behandel).
- Diasepaam, imipramien, klomipramien, sitalopraam en sekere ander medisynes wat gebruik word vir angs, depressie of spierspasma.
- Fenitoïen (gebruik by epilepsie). Jou dokter sal moontlik die fenitoïenkonsentrasie in jou bloed goed dophou as jy begin het met Nexiflux, of as jy ophou om dit te gebruik.
- Sisapried (gebruik vir swak spysvertering en sooibrand).
- Digoksien (hartmedisyne).
- Ysteraanvullings.
- NSAIMs (nie-steroïed anti-inflammatoriese middels), gebruik vir pyn en ontsteking.
- Medisynes wat bloedklonte voorkom, soos warfarien en klopidogrel.
- Metotreksaat ('n medisyne gebruik vir kanker of erge rumatiek).
- Rifampisien ('n antibiotikum wat gebruik word vir tering (TB)).
- Sint Janskruid ('n kruiemiddel wat gebruik word vir depressie).

Nexiflux kan akkurate diagnose met sommige laboratoriumtoetse en prosedures voorkom. Lig altyd jou dokter of professionele gesondheidsorgkundige in dat jy Nexiflux neem.
Indien jou dokter ook amoksisillien en klaritromisien saam met Nexiflux voorgeskryf het om swere te behandel wat veroorsaak word deur 'n infeksie met *Helicobacter pylori* ('n kiem), is dit ook baie belangrik dat jy jou dokter sal inlig oor al die medisyne wat jy tans neem, ook daardie wat jy self aangeskaf het.
Voordat jy begin om enige nuwe medisyne te gebruik (op voorskrif, of nie op voorskrif nie), raadpleeg jou dokter, apteker of professionele gesondheidsorgkundige vir advies.

4. HOE OM NEXIFLUX TE NEEM
Moenie medisyne wat vir jou voorgeskryf is met ander mense deel nie.
Neem Nexiflux altyd presies soos jou dokter dit vir jou voorgeskryf het. As jy nie seker is nie, vra jou dokter of apteker.
Nexiflux is nie bedoel vir die onmiddelike verligting van simptome veroorsaak deur sooibrand nie.
Kinders onder 12 jaar:
Nexiflux word nie aanbeveel vir kinders jonger as 12 jaar oud nie.

Volwassenes en kinders ouer as 12 jaar:
Die gewone dosis is:
Neem een Nexiflux 20 mg tablet daagliks, vir 'n maksimum periode van 14 dae.
Moet nooit meer as 20 mg (een Nexiflux 20 mg tablet) per dag neem nie.

Bejaarde mense:
Dit is onnodig om 'n spesiale dosis te neem as jy bejaard is (ouer as 65 jaar).

Hoe om jou tablette te neem:
Sluk jou tablette heel in, met water.
Jy kan Nexiflux enige tyd van die dag neem, ten minste 30 minute voor 'n maaltyd.
Moenie die tablette kou of fynmaak nie, aangesien die tablette saamgestel is uit bedekte korrels wat nie beskadig mag word nie. Hierdie korrels word individueel bedek om te keer dat die medisyne nie deur die suur in jou maag afgebreek word nie.
- **Indien dit vir jou moeilik is om die tablet heel in te sluk:**

As jy moeilik sluk, kan jy die tablette ook in 'n halfglas nie-gekarboneerde water plaas en dit roer. Roer totdat die tablette gedisintegreer het (die mengsel sal nie helder wees nie) en drink dadelik die water met die korrels. Geen ander vloeistowwe moet gebruik word nie, aangesien die maagsapbestande deklagie dan kan oplos. Spoel die glas met nog 'n bietjie water en drink dit ook dadelik op. Moenie die korreltjies kou nie.
- **As jy nie kan sluk nie:**

Die tablet kan met 'n bietjie water gemeng word en in 'n spuit geplaas word wat die maagbuis direk in jou maag toegedien word.
Jou dokter sal jou inlig hoe lank jou behandeling met Nexiflux sal aanhou. Moenie die behandeling vroeër staak nie, want jou simptome kan terugkeer.
Indien jy die indruk kry dat die effek van Nexiflux te sterk of te swak is, bespreek dit met jou dokter of apteker.

Indien jy meer Nexiflux geneem het as wat jy moes
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospital of gifbeheersentrum.
Neem hierdie pamflet en enige oorblywende tablette saam met jou, sodat die dokter weet wat jy geneem het.
Alhoewel tekens van oordosering verskil, kan jy moontlik swak voel en maagprobleme hê (los stoelgange en buikpyn) en siek voel (naar).

Indien jy vergeet het om 'n dosis Nexiflux te neem
Moenie 'n dubbeldosis neem om op te maak vir vergete individuele dosisse nie.

Effek wanneer behandeling met Nexiflux gestaak moet word
Praat met jou dokter voordat jy ophou om Nexiflux te neem, want jou simptome kan terugkeer.

5. MOONTLIKE NEWE-EFFEKTE
Nexiflux kan newe-effekte hê.
Nie alle newe-effekte wat vir Nexiflux aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak, of jy enige ongunstige effekte ervaar terwyl jy Nexiflux neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige.

Indien enige van die volgende gebeur, staak Nexiflux, vertel jou dokter dadelik daarvan, of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Swelling van die lippe, gesig en oë, buikpyn, braking (opbring), moeilike asemhaling, roggelende bors of hoes (anafilakse), of swelsel onder die vel met rooi hale, brandende, seer, soms jeukende plekke op die vel, toegetrekte keel (angio-edeem).

Al hierdie newe-effekte is baie ernstig. Indien jy daarvan ervaar, kan jy 'n ernstige, moontlik lewensbedreigende allergiese reaksie op Nexiflux hê. Jy kan dringende mediese aandag of hospitalisering benodig.

Lig jou dokter dadelik in as jy die volgende tekens waarneem, of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Griepsimptome soos hoes, koors en hoofpyn, gevolg deur 'n pynlike uitslag wat versprei en blasies vorm. Die blasies kan veroorsaak dat die aangetaste vel afsterf en afskilfer. Die siekte kan die vel laat lyk asof dit verbrand het. Hierdie tekens kan te wyte wees aan die Stevens-Johnson-siekte ('n ernstige, soms noodlottige, ontsteking).
- Vel en die wit van die oog wat geel word as gevolg van lewer- of bloedsiekte (geelsug), of naarheid, braking, verlies aan eetlus, buikpyn, donker urien, liggekleurde stoelgange, moegheid (hepatitis met of sonder geelsug).
- Koors en infeksie – jy kan leukopenie, agranulositose of pansitopenie ('n erge afname is die aantal witbloedselle) hê. Jou dokter sal bloedtoetse aanvra en jou daarvolgens behandel.
- Bloed in die urien, koors, naarheid, swelling, passering van óf meer, óf minder urien. Jy kan ontsteking van die niere hê (interstisiële nefritis). Die ontsteking kan die niere se werking aantas, soos hulle vermoë om afvalstowwe te filtreer. Indien jy dink dat jy enige van hierdie simptome het, kontak jou dokter om te hoor wat jy moet doen.
- Loopmaag, met waterige stoelgange, koors en maagpyn. (Kyk **Wees versigtig met Nexiflux**).

Al hierdie newe-effekte is ernstig. Jy kan dringende mediese aandag benodig.

Sê vir jou dokter as jy enige van die volgende waarneem:
Newe-effekte wat dikwels voorkom:
- Hoofpyn.
- Maagpyn, diarree, hardlywigheid, winderigheid, naarheid of braking (opbring).

Newe-effekte wat minder dikwels voorkom:
- Sproei (wit stippels as gevolg van gisinfeksie) met pyn en ontsteking (rooi weefsel) in die mond, derms en slukderm. Jou dokter kan 'n swamwerende medisyne voorskryf as jy hierdie siekte het.
- Kneus makliker en buitensporig, pers vlekke in die vel, bloei langer na 'n sny, bloei vanself uit die neus of tandvleis. Jy kan trombsitopenie hê (dit is 'n lae bloedplaatjietelling). Jou dokter sal bloedtoetse aanvra en jou daarvolgens behandel.
- Swelling van die voete en enkels.
- Sweet meer.
- 'n Swak en siek gevoel en spierkrampe kan dui op 'n lae natriumkonsentrasie in jou bloed (hiponatremie).
- Probleme met slaap (slapeloosheid of slaperigheid), 'n gevoel van onrustigheid, verwarring of neerslagtigheid, aggressie en hallusinasies (sien, voel of hoor dinge wat nie bestaan nie).
- Smaakverandering, duiseligheid, prikkeling in die hande en/of voete – "spelde en naalde" gevoel.
- Oogskerpte aangetas; dowwe visie.
- Middeloor balansversteuring.
- Asemhalingsprobleme; roggelende bors of kortasemigheid.
- Droë mond.
- Veluitslag en vel gevoelig, bulterige uitslag (galbulte) en jeuk, haarverlies.
- Gewrigspyne of spierpyne; swak spiere of bene, wat die kans groter maak om jou pols, ruggraat en heup te breek as jy beseer word.
- Vergroting van borste by mans.
- 'n Siek gevoel en gebrek aan energie, sweet meer as gewoonlik.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet vermeld word nie, lig asseblief jou dokter of apteker in.

6. BERGING EN WEGDOENING VAN NEXIFLUX
Bêre alle medisyne buite bereik van kinders.
Bewaar teen of benede 25 ºC op 'n droë plek, in die oorspronklike verpakking. Hou die stulpstroke in die karton totdat dit benodig word vir gebruik. Hou die houer diggeslote.
Moenie in die badkamer bêre nie.
Moenie Nexiflux gebruik na die vervaldatum wat op die karton en stulpstroke gedruk is nie. Neem ongebruikte of vervalde medisyne terug na jou apteker om veilig daarvan ontslae te raak. Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

7. AANBIEDING VAN NEXIFLUX
Nexiflux 20 maagsapbestande tablette word verpak in een van die volgende verpakkingsmateriale, in pakkies met 14 tablette:
Stulpstroke, bestaande uit 'n silwerkleurige skoon aluminiumfoelie en 'n silwerkleurige koud-gevormde aluminium stulpstrokie (Alu/Alu-stulpstrokie), verpak in 'n kartonhouer.
Stulpstroke, bestaande uit 'n silwerkleurige skoon aluminiumfoelie blad en 'n deursigtige, kleurlose, PVC/PVDC blad, verpak in 'n kartonhouer.
Nie alle verpakkingsgroottes word noodwendig gelyktydig bemark nie.

8. IDENTIFIKASIE VAN NEXIFLUX
Nexiflux 20: Ligpienk, bedekte, 6,55 x 13,6 mm, ellipsvormige, bikonvekse, maagsapbestande tablet.

9. REGISTRASIENOMMERS
Nexiflux 20: 48/11.4.3/0436

10. NAAM EN ADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKATE
Astral Pharma (Pty) Ltd 125 Meade Straat
1ste Vloer Beacon Place George
6529

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