PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NEXIPRAZ 20 Gastro-resistant tablet

The active substance is esomeprazole magnesium 20,7 mg equivalent to esomeprazole 20 mg.

Contains 30 mg sucrose per tablet:

NEXIPRAZ 40 Gastro-resistant tablet

The active substance is esomeprazole magnesium 41,4 mg equivalent to esomeprazole 40 mg.

Contains 60 mg sugar per tablet

Read all of this leaflet carefully before you start taking NEXIPRAZ tablets.

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

1. WHAT NEXIPRAZ IS AND WHAT IT IS USED FOR

NEXIPRAZ contains esomeprazole which belongs to a group of medicines known as proton pump inhibitors.

NEXIPRAZ tablets are used:

- in the treatment of gastroesophageal reflux disease (a condition in which gastric content may rise up to the oesophagus and which can be associated with oesophagitis) caused by acid secretion and the associated symptoms such as heartburn, acidic belches and pain on swallowing.
- in the long-term treatment and in the prevention of reflux oesophagitis (a condition in which backwash of gastric content in oesophagus leads to inflammation and pain).
- in combination with appropriate medicines (antibacterials) for healing *Helicobacter pylori* (*Helicobacter pylori*- a microorganism which may cause gastric or duodenal ulcers) associated duodenal ulcer and prevention of peptic ulcers reappearing in patients with *Helicobacter pylori* associated ulcers
- in the healing and prevention of gastric and duodenal ulcers caused by anti-inflammatory medicines in some patients needing continuous treatment with anti-inflammatory medicines (e.g. aspirin and ibuprofen)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEXIPRAZ

Do not take NEXIPRAZ:

- if you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of **NEXIPRAZ** tablets (see section "**WHAT NEXIPRAZ CONTAINS**" for further information).
- if you are allergic to any other proton pump inhibitors (medicines that decrease the secretion of acid from the stomach).
- if you are taking atazanavir or nelfinavir for HIV.

Warnings and precautions

Special care should be taken with **NEXIPRAZ**

- if you suffer or have recently suffered from any of the following symptoms: unintentional weight loss, recurrent vomiting or vomiting of blood, or dark stool or difficulty in swallowing. Your doctor may

perform additional investigations in order to diagnose your condition and/or exclude malignant disease.

- **NEXIPRAZ** is not indicated for mild gastric complaints like mild pain in the abdomen, abdominal fullness and feeling full earlier than expected when eating due to nervousness, tension, or anxiety.
- if you take **NEXIPRAZ** tablets on a long-term basis (longer than 1 year), your doctor may keep you under regular monitoring.
- If you are taking clopidogrel for blood clotting.

Diarrhoea: **NEXIPRAZ** may increase your risk of getting severe diarrhoea. This diarrhoea may be caused by an infection (*Clostridium difficile*) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.

Bone fractures: People who take Proton Pump Inhibitor medicines, such as in **NEXIPRAZ,** for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist, or spine. You should take **NEXIPRAZ** exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your doctor about your risk of bone fracture if you take **NEXIPRAZ**.

Low magnesium levels in your body: Low magnesium can happen in some people who take a proton pump inhibitor medicine (such as **NEXIPRAZ**) for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium. Tell your doctor right away if you have any of the following symptoms: seizures, dizziness, tiredness, abnormal or fast heartbeat, muscle cramps or spasm.

Vitamin B deficiency: **NEXIPRAZ** reduces the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B12 properly. Talk to your doctor about the possibility of vitamin B12 deficiency if you have been taking **NEXIPRAZ** for a long time (more than 3 years).

Subacute chronic lesions on the skin and mucous membranes: Proton pump inhibitor medicines, such as **NEXIPRAZ,** are associated with very infrequent cases of this condition. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by pain in joints, the patient should seek medical help immediately and the health care professional should consider stopping **NEXIPRAZ**. The condition

after previous treatment with a proton pump inhibitor may increase the risk of the condition with other proton pump inhibitors.

Effect on the kidneys: Proton pump inhibitor medicines, such as **NEXIPRAZ,** may rarely cause interstitial nephritis which can lead to inflammation that affects the tubules of the kidneys and the tissues that surround them. This condition may progress to kidney failure and is not necessarily reversed when treatment is discontinued.

Other medicines and NEXIPRAZ:

Always tell your health care provider if you are taking any other medicine. (This includes all complimentary medicines).

- atazanavir or nelfinar, used to treat HIV infection.
- ketoconazole, itraconazole or voriconazole, used to treat fungal infections since **NEXIPRAZ** may affect its concentration in your body.
- to thin your blood, such as warfarin. It may be necessary to monitor your blood coagulation more often.
- to prevent blood clots, such as clopidogrel. **NEXIPRAZ** and clopidogrel should not be used together as the effect of clopidogrel may be reduced.
- benzodiazepines, such as diazepam (used in the treatment of anxiety) and phenytoin (used to treat seizures).
- citalopram, imipramine or clomipramine, used to treat depression.
- methotrexate, a chemotherapy medicine used in high doses to treat cancer.
- tacrolimus, used for organ transplantation.
- erlotinib, used to treat cancer.
- digoxin, used for heart problems.
- cilostazol, used to treat pain in your legs when you walk which is caused by an insufficient blood supply.
- rifampicin, used to treat tuberculosis.
- St John’s wort, used to treat depression.

- cisapride, used for indigestion and heartburn.
- If your doctor has prescribed amoxicillin and clarithromycin to get rid of your *Helicobacter pylori* in order to heal your ulcer, it is essential that you tell your doctor about any other medicines you are taking.
- **NEXIPRAZ** contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Pregnancy and breastfeeding

Do not take **NEXIPRAZ** if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **NEXIPRAZ**.

Driving and using machines

NEXIPRAZ may cause dizziness and may affect the ability to drive or use machines.

3. HOW TO TAKE NEXIPRAZ

Always take NEXIPRAZ exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

You should swallow the tablet(s) whole, with water. Do not crush, break or chew the tablet(s).

If you have difficulty in swallowing, the tablets can also be dispersed in half a glass of non-carbonated water. No other liquids should be used as the enteric coating may be dissolved. Stir until the tablets disintegrate and drink the liquid with the pellets immediately or within 30 minutes. Rinse the glass with half a glass of water and drink. The pellets must not be chewed or crushed.

The usual dose of **NEXIPRAZ** is mentioned below:

Symptoms of gastroesophageal reflux disease

The usual dose for the treatment of the symptoms of gastroesophageal reflux disease is one tablet of **NEXIPRAZ** 20 mg per day. Your doctor will tell you how long to continue taking the medicine.

Treatment of gastroesophageal reflux disease

The usual dose for the treatment of acid reflux is 40 mg (2 x 20 mg tablets or 1 x 40 mg tablet) per day for 4 weeks. Your doctor will tell you how long to continue taking the medicine.

Long-term treatment to prevent reappearance of reflux oesophagitis

For long term treatment the recommended dose is 1 tablet of **NEXIPRAZ** 20 mg once daily

In combination with appropriate medicines (antibacterials) for healing *Helicobacter pylori*

NEXIPRAZ 20 mg tablet two times a day for 7 days.

Prevention and healing of gastric and duodenal ulcers caused by anti-inflammatory medicines (NSAIDs) in patients at risk

The recommended dose is 1 to 2 tablets of **NEXIPRAZ** 20 mg (or 1 tablet of **NEXIPRAZ** 40 mg) daily.

If you have the impression that the effect of **NEXIPRAZ** is too strong or too weak, talk to your doctor or pharmacist.

Children

NEXIPRAZ should not be used in children younger than 12 years.

If you take more NEXIPRAZ than you should

If you take more NEXIPRAZ 20 mg or 40 mg tablets than you should call your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take along any tablets that are left, the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take NEXIPRAZ

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten tablet. If you miss several doses, contact your doctor.

Effects when treatment with NEXIPRAZ is stopped

Do not stop taking **NEXIPRAZ** unless on your doctor's advice.

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

4. POSSIBLE SIDE EFFECTS

NEXIPRAZ can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **NEXIPRAZ**. 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:

Less frequent:

- Yellowing of the skin and whites of the eyes, also called jaundice.
- Skin reactions (including skin rashes, hives, inflammation or swelling, blistering, peeling, loosening of skin, red skin lesions, often with a purple centre, sores or ulcers).
- Blood disorders associated with sore throat, fever or chills; cough or hoarseness; lower back or side pain; painful or difficult urination; unusual bleeding or bruising; black, tarry stools; blood in urine or stools; pinpoint red spots on skin.

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

Tell your doctor if you notice any of the following:

Frequent:

Headache, abdominal pain, diarrhoea, gas, nausea/vomiting, constipation, skin rashes.

Less frequent:

Dizziness, sleepiness, unusual tiredness or weakness, trouble in sleeping, confusion, agitation, hallucinations (seeing, hearing, or feelings things that are not there), depression, aggression, bronchospasm (suddenly feeling wheezy or short of breath), dry mouth, taste disturbances, sores in the mouth, blurred vision, hair loss, increased sweating, impotence, enlarged breasts in men, vertigo (sense of constant movement of self or surroundings), joint or muscle pain, fracture of the hip, wrist or spine (see **Take special care with NEXIPRAZ**), changes in blood tests that check how the liver is working, blood problems such as a reduced number of white blood cells or platelets, low levels of sodium in the blood, an infection called “thrush” which can affect the gut, severe kidney problems.

Frequency unknown:

Low magnesium levels in your body (see **Take special care with NEXIPRAZ**), severe liver problems leading to liver failure and inflammation of the brain.

You may also get severe diarrhoea characterised by watery stools, stomach pain, fever (*Clostridium difficile* associated diarrhoea).

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. 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 providing information on the safety of **NEXIPRAZ.**

5. HOW TO STORE NEXIPRAZ

Store at or below 25 °C, protected from moisture. Do not remove the blisters from the carton until required for use.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not store in bathrooms in order to protect from moisture.

Do not use after the expiry date stated on the label.

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 NEXIPRAZ contains

The active substance is esomeprazole magnesium 20,7 mg and 41,4 mg equivalent to esomeprazole 20 mg and 40 mg respectively.

The other ingredients are sucrose, crospovidone, diethlyphthalate, hydroxypropyl cellulose, hypromellose phthalate, polyethylene glycol, purified talc, microcrystalline cellulose, povidone and sodium stearyl fumarate. Film coating material: Opadry brown, polyethylene glycol.

What NEXIPRAZ looks like and contents of the pack

NEXIPRAZ 20

Light brick red to brown coloured, oval, biconvex, film coated tablets with '**E5'** debossed on one side and plain on the other side.

NEXIPRAZ 40

Light brick red to brown coloured, oval, biconvex, film coated tablets with 'E6' debossed on one side and plain on the other side.

Blister pack

The carton contains 14, 28 or 30 tablets packed in cold form blister strips or desiccant embedded cold form blister strips. Each blister strip contains 7 or 10 tablets.

Plastic HDPE bottle

The carton contains white opaque HDPE bottle with screw cap closure containing 30 tablets.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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So

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Registration Numbers

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PASIËNT INLIGTINGSTUK

SKEDULERINGSTATUS : S4

NEXIPRAZ 20 Gastries-weerstandbiedende tablet

Die aktiewe bestanddeel is esomeprasool magnesium 20,7 mg gelykstaande aan esomeprasool 20 mg.

Bevat 30 mg sukrose per tablet:

NEXIPRAZ 40 Gastries-weerstandbiedende tablt

Die aktiewe bestanddeel is esomeprasool magnesium 41,4 mg gelykstaande aan esomeprazole 40 mg.

Bevat 60 mg sukrose per tablet

Lees die hele pamflet noukeurig deur voordat jy NEXIPRAZ tablette begin neem.

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- **NEXIPRAZ** is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat **NEXIPRAZ** is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy **NEXIPRAZ** neem
3. Hoe om **NEXIPRAZ** te neem
4. Moontlike newe-effekte
5. Hoe om **NEXIPRAZ** te berg
6. Inhoud van die pakkie en ander inligting

1. WAT NEXIPRAZ IS EN WAARVOOR DIT GEBRUIK WORD

NEXIPRAZ bevat esomeprasool wat aan 'n groep medisyne behoort wat bekend staan as protonpompinhibeerders.

NEXIPRAZ tablette word gebruik:

- in die behandeling van gastro-oesofageale refluksiekte ('n toestand waarin die maaginhoud tot by die slukderm kan styg en wat met slukdermontsteking geassosieer kan word) wat veroorsaak word deur suurafskeiding en die gepaardgaande simptome soos sooibrand, suur opblaas en pyn tydens sluk.
- in die langtermyn-behandeling en in die voorkoming van refluks-esofagitis ('n toestand waarin terugspoeling van maaginhoud in slukderm lei tot inflammasie en pyn).
- in kombinasie met toepaslike medisyne (antibakteriese middels) vir die genesing van *Helicobacter pylori* (*Helicobacter pylori*- 'n mikro-organisme wat maag of duodenale ulkusse kan veroorsaak) geassosieerde duodenale ulkusse en voorkoming van maagsere wat weer verskyn by pasiënte met *Helicobacter pylori*-geassosieerde ulkusse.
- in die genesing en voorkoming van maag- en duodenale ulkusse wat veroorsaak word deur anti-inflammatoriese medisyne by sommige pasiënte wat deurlopende behandeling met anti-inflammatoriese medisyne benodig (bv. aspirien en ibuprofen).

2. WAT JY MOET WEET VOOR JY NEXIPRAZ NEEM

Moenie NEXIPRAZ neem nie:

- as jy allergies (hipersensitief) is vir esomeprasool of enige van die ander bestanddele van **NEXIPRAZ** tablette (sien afdeling “WAT **NEXIPRAZ** BEVAT” vir verdere inligting).
- as jy allergies is vir enige ander protonpomp-inhibeerders (medisyne wat die afskeiding van suur uit die maag verminder).
- as jy atazanavir of nelfinavir vir MIV neem.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met **NEXIPRAZ**

- as u enige van die volgende simptome ly of onlangs gely het: onbedoelde gewigsverlies, herhalende braking of braking van bloed, of donker stoelgang of probleme om te sluk. Jou

dokter kan bykomende ondersoeke doen om jou toestand te diagnoseer en/of kwaadaardige siekte uit te sluit.

- **NEXIPRAZ** is nie aangedui vir ligte maagklagtes soos ligte pyn in die buik, abdominale volheid en versadigde gevoel vroeër as wat verwag is wanneer jy eet as gevolg van senuweeagtigheid, spanning of angs nie.
- as jy **NEXIPRAZ**-tablette op 'n langtermyn-basis (langer as 1 jaar) neem, kan jou dokter jou gereeld onder monitering hou.
- as jy clopidogrel neem vir bloedstolling.

Diarree: **NEXIPRAZ** kan jou risiko verhoog om erge diarree te kry. Hierdie diarree kan veroorsaak word deur 'n infeksie (Clostridium difficile) in jou ingewande. Bel jou dokter dadelik as jy waterige stoelgang, maagpyn en koors het wat nie weggaan nie.

Beenfrakture: Mense wat Protonpomp-inhibeerdermedisyne, soos in **NEXIPRAZ,** vir 'n lang tydperk ('n jaar of langer) neem, kan 'n verhoogde risiko hê van frakture van die heup, pols of ruggraat. Jy moet **NEXIPRAZ** neem presies soos voorgeskryf, teen die laagste dosis moontlik vir jou behandeling en vir die kortste tyd wat nodig is. Praat met jou dokter oor jou risiko van beenfraktuur as jy **NEXIPRAZ** neem.

Lae magnesiumvlakke in jou liggaam: Lae magnesium kan voorkom by sommige mense wat 'n protonpompremmermedisyne (soos **NEXIPRAZ**) vir ten minste 3 maande neem. As lae magnesiumvlakke voorkom, is dit gewoonlik na 'n jaar se behandeling. Jy mag of mag nie simptome van lae magnesium hê nie. Vertel jou dokter dadelik as jy enige van die volgende simptome het: aanvalle, duiseligheid, moegheid, abnormale of vinnige hartklop, spierkrampe of spasma.

Vitamien B-tekort: **NEXIPRAZ** verminder die hoeveelheid suur in jou maag. Maagsuur is nodig om vitamien B12 behoorlik te absorbeer. Praat met jou dokter oor die moontlikheid van vitamien B12-tekort as jy **NEXIPRAZ** vir 'n lang tyd (meer as 3 jaar) gebruik.

Subakute chroniese letsels op die vel en slymvliese: Protonpomp-inhibeermiddels, soos **NEXIPRAZ,** word geassosieer met baie seldsame gevalle van hierdie toestand. As letsels voorkom, veral in son-

blootgestelde areas van die vel, en as dit gepaard gaan met pyn in gewrigte, moet die pasiënt onmiddellik mediese hulp soek en die gesondheidswerker moet dit oorweeg om **NEXIPRAZ** te stop. Die toestand na vorige behandeling met 'n protonpompinhibeerder kan die risiko van die toestand met ander protonpompinhibeerders verhoog.

Effek op die niere: Protonpomp-inhibeermiddels, soos **NEXIPRAZ**, kan selde interstisiële nefritis veroorsaak wat kan lei tot inflammasie wat die buisies van die niere en die weefsels wat hulle omring, aantas. Hierdie toestand kan tot nierversaking vorder en word nie noodwendig omgekeer wanneer behandeling gestaak word nie.

Ander medisyne en NEXIPRAZ:

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplimentêre medisyne in).

- atazanavir of nelfinar, wat gebruik word om MIV-infeksie te behandel.
- ketokonasool, itrakonasool of vorikonasool, wat gebruik word om swaminfeksies te behandel aangesien **NEXIPRAZ** die konsentrasie daarvan in jou liggaam kan beïnvloed.
- om jou bloed te verdun, soos warfarin. Dit mag nodig wees om jou bloedstolling meer gereeld te monitor.
- om bloedklonte, soos klopidogrel, te voorkom. **NEXIPRAZ** en klopidogrel moet nie saam gebruik word nie, aangesien die effek van klopidogrel verminder kan word.
- bensodiasepiene, soos diasepam (gebruik in die behandeling van angs) en fenitoïen (gebruik om aanvalle te behandel).
- citalopram, imipramien of klomipramien, gebruik om depressie te behandel.
- metotreksaat, 'n chemoterapie-medisyne wat in hoë dosisse gebruik word om kanker te behandel.
- takrolimus, gebruik vir orgaanoorplanting.
- erlotinib, gebruik om kanker te behandel.
- digoksien, gebruik vir hartprobleme.

- cilostazol, gebruik om pyn in jou bene te behandel wanneer jy loop wat veroorsaak word deur 'n onvoldoende bloedtoevoer.
- rifampisien, gebruik om tuberkulose te behandel.
- St John's wort, gebruik om depressie te behandel.
- cisapried, gebruik vir spysvertering en sooibrand.
- As jou dokter amoksisillien en klaritromisien voorgeskryf het om van jou *Helicobacter pylori* ontslae te raak om jou ulkus te genees, is dit noodsaaklik dat jy jou dokter vertel van enige ander medisyne wat jy neem.
- **NEXIPRAZ** bevat sukrose wat 'n uitwerking op die beheer van jou bloedsuiker kan hê as jy diabetes mellitus het.

Swangerskap en borsvoeding

Moenie **NEXIPRAZ** neem as jy swanger is of jou baba borsvoed nie.

As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidswerker vir advies voordat **NEXIPRAZ** geneem word.

Bestuur en gebruik van masjiene

NEXIPRAZ kan duiseligheid veroorsaak en kan die vermoë om te bestuur of masjiene te gebruik beïnvloed.

3. HOE OM NEXIPRAZ TE NEEM

Neem **NEXIPRAZ** altyd presies soos jou dokter jou voorgeskryf het. Jy moet jou dokter of apteker raadpleeg as jy onseker is.

Jy moet die tablet(te) heel, met water sluk. Moenie die tablet(te) vergruis, breek of kou nie. As jy sukkel om te sluk, kan die tablette ook in 'n halwe glas nie-koolsuurhoudende water versprei word. Geen ander vloeistowwe moet gebruik word nie, aangesien die enteriese laag opgelos mag word. Roer totdat die tablette disintegreer en drink die vloeistof saam met die pille onmiddellik of binne 30 minute. Spoel die glas uit met 'n halwe glas water en drink. Die korrels moet nie gekou of fyngemaak word nie.

Die gewone dosis **NEXIPRAZ** word hieronder genoem:

Simptome van gastro-oesofageale refluksiekte

Die gewone dosis vir die behandeling van die simptome van gastro-sofageale refluksiekte is een tablet **NEXIPRAZ** 20 mg per dag. Jou dokter sal jou vertel hoe lank jy moet aanhou om die medisyne te neem.

Behandeling van gastro-oesofageale refluksiekte

Die gewone dosis vir die behandeling van suur refluks is 40 mg (2 x 20 mg tablette of 1 x 40 mg tablet) per dag vir 4 weke. Jou dokter sal jou vertel hoe lank jy moet aanhou om die medisyne te neem.

Langtermynbehandeling om die herverskyning van refluks-esofagitis te voorkom

Vir langtermynbehandeling is die aanbevole dosis 1 tablet **NEXIPRAZ** 20 mg een keer per dag

In kombinasie met toepaslike medisyne (antibakteriese middels) vir die genesing van *Helicobacter pylori*

NEXIPRAZ 20 mg tablet twee keer per dag vir 7 dae.

Voorkoming en genesing van maag- en duodenale ulkusse wat veroorsaak word deur anti-inflammatoriese medisyne (NSAIDs) by pasiënte in gevaar

Die aanbevole dosis is 1 tot 2 tablette **NEXIPRAZ** 20 mg (of 1 tablet **NEXIPRAZ** 40 mg) daagliks.

As jy die indruk het dat die effek van NEXIPRAZ te sterk of te swak is, praat met jou dokter of apteker.

Kinders

NEXIPRAZ moet nie by kinders jonger as 12 jaar gebruik word nie.

As jy meer NEXIPRAZ neem as wat jy moet

As jy meer **NEXIPRAZ** 20 mg of 40 mg tablette neem as wat jy jou dokter of apteker moet skakel. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem enige tablette wat oorbly, die houer en die etiket saam sodat die hospitaal maklik kan sê watter medisyne jy geneem het.

As jy vergeet om NEXIPRAZ te neem

As jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou, tensy dit amper tyd is vir jou volgende dosis. Moenie 'n dubbele dosis neem om op te maak vir 'n vergete tablet nie. As jy verskeie dosisse mis, kontak jou dokter.

Effekte wanneer behandeling met NEXIPRAZ gestaak word

Moenie ophou om **NEXIPRAZ** te neem nie, tensy op jou dokter se advies.

As jy enige verdere vrae het oor die gebruik van **NEXIPRAZ**, vra jou dokter of apteker.

4. MOONTLIKE NEWE-EFFEKTE

NEXIPRAZ kan newe-effekte hê.

Nie alle newe-effekte wat vir **NEXIPRAZ** aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u **NEXIPRAZ** neem, raadpleeg asseblief u dokter, apteker of ander gesondheidswerker vir advies.

As enige van die volgende gebeur, hou op om **NEXIPRAZ** te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond, tong of keel wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of jeuk,
- flou word.

Dit is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op **NEXIPRAZ** gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

Minder gereeld:

- Vergeling van die vel en wit van die oë, ook genoem geelsug.
- Velreaksies (insluitend veluitslag, korwe, inflammasie of swelling, blase, afskilfering, losmaak van die vel, rooi velletsels, dikwels met 'n pers middelpunt, sere of maagsere).

- Bloedafwykings wat verband hou met seer keel, koors of kouekoors; hoes of heesheid; lae rug of sypyn; pynlike of moeilike urinering; ongewone bloeding of kneusing; swart, teeragtige stoelgange; bloed in urine of stoelgang; identifiseer rooi kolle op die vel.

Dit is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:

Gereeld:

Hoofpyn, buikpyn, diarree, gas, naarheid/braking, hardlywigheid, veluitslag.

Minder gereeld:

Duiseligheid, slaperigheid, ongewone moegheid of swakheid, probleme om te slaap, verwarring, opwinding, hallusinasies (sien, hoor of voel dinge wat nie daar is nie), depressie, aggressie, brongospasma (skielik hygende gevoel of kortasem), droë mond, smaakversteurings, sere in die mond, versteurde visie, haarverlies, verhoogde sweet, impotensie, vergrote borste by mans, vertigo (gevoel van konstante beweging van self of omgewing), gewrig- of spierpyn, fraktuur van die heup, pols of ruggraat (sien **Wees veral versigtig met NEXIPRAZ**), veranderinge in bloedtoetse wat kyk hoe die lewer werk, bloedprobleme soos 'n verminderde aantal witbloedselle of bloedplaatjies, lae vlakke van natrium in die bloed, 'n infeksie genaamd "sproei" wat kan affekteer die derm, ernstige nierprobleme.

Frekwensie onbekend:

Lae magnesiumvlakke in jou liggaam (sien **Wees veral versigtig met NEXIPRAZ**), ernstige lewerprobleme wat lei tot lewerversaking en inflammasie van die brein.

Jy kan ook ernstige diarree kry wat gekenmerk word deur waterige stoelgang, maagpyn, koors (*Clostridium difficile*-geassosieerde diarree).

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

Rapportering van newe-effekte

As jy newe-effekte kry, praat met jou dokter. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “6.04 Adverse Drug Reaction Reporting Form” wat aanlyn gevind word onder SAHPRA se publikasies: https:www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om inligting oor die veiligheid van NEXIPRAZ te verskaf.

5. HOE OM NEXIPRAZ TE BERG

Berg by of onder 25 °C, beskerm teen vog. Moenie die stulpstroke uit die karton verwyder voordat dit benodig word vir gebruik nie.

HOU BUITE DIE BEREIK EN SIG VAN KINDERS.

Moet nie in badkamers stoor nie om teen vog te beskerm.

Moet nie na die vervaldatum soos op die etiket aangebring gebruik nie.

6. INHOUD VAN DIE PAK EN ANDER INLIGTING

Wat NEXIPRAZ bevat

Die aktiewe bestanddeel is esomeprazole magnesium 20,7 mg en 41,4 mg gelykstaande aan esomeprazole 20 mg en 40 mg onderskeidelik.

Die ander bestanddele is sukrose, krospovidoon, dietliftalaat, hidroksipropielsellulose, hipromelloseftalaat, poliëtileenglikol, gesuiwerde talk, mikrokristallyne sellulose, povidoon en natriumstearielfumaraat. Filmbedekkingsmateriaal: Opadry-bruin, poliëtileenglikol.

Hoe lyk NEXIPRAZ en die inhoud van die verpakking

NEXIPRAZ 20

Ligte baksteenrooi tot bruinkleurige, ovaal, bikonvekse, filmbedekte tablette met 'E5' ingedruk aan die een kant en effe aan die ander kant.

NEXIPRAZ 40

Ligte baksteenrooi tot bruinkleurige, ovaal, bikonvekse, filmbedekte tablette met 'E6' ingedruk aan die een kant en effe aan die ander kant.

Stulpverpakking

Die karton bevat 14, 28 of 30 tablette verpak in koue vorm stulpstrokies of droogmiddel ingebedde kouevorm stulpstroke. Elke stulpstrook bevat 7 of 10 tablette.

HDPE Plastiek bottel

Die karton bevat ‘n wit ondeursigtige HDPE-bottel met skroefdop sluiting wat 30 tablette bevat.

Houer van Sertifikaat van Registrasie

Ranbaxy Pharmaceuticals (Edms.) Bpk

'n Sun Pharma-maatskappy

Lautreweg 14, Stormill Uitbr 1

Roodepoort, 1724

Suid-Afrika

Hierdie pamflet is laas hersien in

14 Augustus 2022

Registrasienommers

NEXIPRAZ 20: 45/11.4.3/0125

NEXIPRAZ 40: 45/11.4.3/0126