Each vial contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PANTOCID® 40 mg INJECTION

Lyophillised Powder for Injection

Pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole

Sugar free

Read all of this leaflet carefully before you are given PANTOCID® 40 mg INJECTION

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

What is in this leaflet

1. What **PANTOCID® 40 mg INJECTION** is and what it is used for
2. What you need to know before you are given **PANTOCID® 40 mg INJECTION**
3. How to take **PANTOCID® 40 mg INJECTION**
4. Possible side effects
5. How to store **PANTOCID® 40 mg INJECTION**
6. Contents of the pack and other information

1. WHAT PANTOCID® 40 MG INJECTION IS AND WHAT IT IS USED FOR

PANTOCID® 40 mg INJECTION contains pantoprazole which belongs to a group of medicines known as proton pump inhibitors.

PANTOCID® 40 mg INJECTION is used to treat certain conditions in which there is too much acid in the stomach. It is used to treat duodenal and gastric ulcers, reflux oesophagitis and Zollinger-Ellison Syndrome. **PANTOCID® 40 mg INJECTION** works by decreasing the amount of acid produced by the stomach.

2. PANTOCID® 40 mg INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of **PANTOCID® 40 mg INJECTION**.

- If you have serious liver problems
- **PANTOCID® 40 mg INJECTION** should not be given to children.

Warnings and precautions

Tell your doctor or health care provider before being given **PANTOCID® 40 mg INJECTION:**

- You have liver problems. Your liver enzymes should be monitored during therapy. In the case of a rise in your liver enzymes, **PANTOCID® 40 mg INJECTION** should be discontinued.
- You have a gastric ulcer or a serious disease of your oesophagus (the tube that delivers food from your mouth to your stomach).
- You have been taking any acid-blocking medicines over a long period of time (i.e. longer than 3 years).
- Prolonged treatment with **PANTOCID® 40 mg INJECTION** may cause low serum magnesium levels with symptoms such as fatigue, dizziness, delirium and convulsions.
- Your doctor will administer **PANTOCID® 40 mg INJECTION** to you as it is to be used for a short period, your symptoms continue in spite of your treatment. Your doctor may decide that you need some tests to rule out malignant disease, because **PANTOCID® 40 mg INJECTION** also alleviates the symptoms of cancer and could cause a delay in diagnosing it.
- If you receive long-term treatment with **PANTOCID® 40 mg INJECTION**, you are at risk of fractures of the hip, wrist or spine.
- You have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- You are due to have a specific blood test measuring Chromogranin A.

Other medicines and PANTOCID® 40 mg INJECTION:

Always tell your health care provider if you are taking any other medicines (this include complementary or traditional medicines).

- **PANTOCID® 40 mg INJECTION** may reduce the absorption of certain medicines used to treat fungal infections, such as ketoconazole and itraconazole.
- **PANTOCID® 40 mg INJECTION** may decrease the amount of atazanavir or nelfinavir, used to treat HIV infection.

- Medicines to thin your blood such as warfarin. **PANTOCID® 40 mg INJECTION** may alter the effect of these medicines so your doctor may monitor how well your blood clots.
- **PANTOCID® 40 mg INJECTION** may increase the levels of methotrexate (high doses used in the treatment of certain cancers) and possibly lead to methotrexate toxicities.
- Fluvoxamine (used to treat depression and other psychiatric diseases).
- Rifampicin (used to treat infections).
- St John's wort (*Hypericum perforatum*) (used to treat mild depression

PANTOCID® 40 mg INJECTION with food or drink

Food does not affect **PANTOCID® 40 mg INJECTION** function.

Pregnancy and breastfeeding:

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 health care provider for advice before receiving this medicine. Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

PANTOCID® 40 mg INJECTION may cause dizziness and disturbances in vision (blurred vision). Do not drive a vehicle or operate machinery until you know how **PANTOCID® 40 mg INJECTION** will affect you.

3. HOW TO RECEIVE PANTOCID® 40 MG INJECTION

You will not be expected to give yourself **PANTOCID® 40 mg INJECTION.** It will be given to you by a person who is qualified to do so. Your doctor will decide on the suitable dose, based on your condition. The normal dose is 40 mg (one vial).

If you receive more PANTOCID® 40 mg INJECTION than you should:

Since a healthcare professional will administer **PANTOCID® 40 mg INJECTION**, he/she will control the dosage. However, in the event of an overdosage, your doctor will manage any symptoms of the overdosage.

4. POSSIBLE SIDE EFFECTS

PANTOCID® 40 mg INJECTION can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while receiving this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop receiving **PANTOCID® 40 mg INJECTION** 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 **PANTOCID® 40 mg INJECTION**. 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:

Side effects with an unknown frequency:

- Severe skin reactions, such as Stevens-Johnson syndrome, erythema multiforme or Lyell syndrome.
- Inflammation of the kidney (characterised by blood in the urine, fever, increased or decreased urine output, drowsiness, confusion, coma, nausea, vomiting).
- Yellowing of the skin and eyes (also called jaundice).
- Low levels of magnesium in your body with symptoms such as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or an increased heart rate.
- Increased risk for gastrointestinal infections, with accompanied diarrhoea.

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

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring frequently:

- Small growths (polyps) in the inner lining of the stomach.
- Pain at the site of the injection.

Side effects occurring less frequently:

- Blood disorders such as leukopenia (a low white blood cell count) or thrombocytopenia (decreased number of platelets in the blood).

- Increased liver enzymes, triglycerides (a type of fat found in your blood) or body temperature.
- Headache.
- Abdominal pain, diarrhoea, constipation, flatulence.
- Feeling depressed, sleep disorders, disorientation.
- Dizziness, blurred vision.
- Distortion or complete lack of your sense of taste.
- Changes in your weight.
- Dry mouth.
- Bloating, swelling of the abdomen.
- Skin rash with red, raised itchy bumps, hives.
- Swelling of the hands, arms, legs and feet.
- Raised body temperature.
- Nausea (feeling sick), vomiting (being sick), dry mouth.
- Muscle or joint pain.
- Enlargement of breasts in men or boys (Gynecomastia).
- Loss of energy or feeling week.
- Feeling tired.
- a general feeling of discomfort, illness, or unease whose exact cause is difficult to identify.

Side effects with an unknown frequency:

- A sudden loss of vision.
- Confusion, seeing or hearing things that are not there.
- Pins and needles, burning sensation or numbness.
- Sensitivity of your skin when exposed to sunlight.

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 **PANTOCID® 40 mg INJECTION.**

Each vial contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

5. HOW TO STORE PANTOCID® 40 MG INJECTION

Store at or below 25 °C, protect from light.

Discard any unused solution.

Do not receive **PANTOCID® 40 mg INJECTION** after the expiry date stated on the label.

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

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What PANTOCID® 40 mg INJECTION contains:

Active ingredient: Pantoprazole sodium sesquihydrate.

Inactive ingredients: Water for injection, nitrogen.

What PANTOCID 40 MG INJECTION looks like and contents of the pack

PANTOCID® 40 mg INJECTION: A white to off-white lyophilised cake in a 10 mL colourless glass vial for intravenous injection.

The reconstituted solution is a clear yellowish solution.

One, five or ten vials are packed into an outer carton.

Holder of the Certificate of Registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext. 1, Roodepoort

Johannesburg 1724

011 495 0100

This leaflet was last revised in

12 February 2024

Registration number

PANTOCID® 40 mg INJECTION: A40/11.4.3/0072

Each vial contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

Namibia:

PANTOCID® 40 mg INJECTION: NS2 Reg. no.: 06/11.4.3/0332

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

PANTOCID® 40 mg INJECTION

Gevriesdroogde Poeier vir Inspuiting

Natriumpantoprasool-seskwihidraat gelykstaande aan 40 mg pantoprasool
Suikervry

Lees die hele inligtingstuk noukeurig deur voordat PANTOCID® 40 mg INJECTION aan jou toegedien word

- Hou hierdie inligtingstuk. Jy sal dit moontlik weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgvoorsiener as jy verdere vrae het.

Wat is in hierdie inligtingstuk

1. Wat **PANTOCID® 40 mg INJECTION** is en waarvoor word dit gebruik
2. Wat jy moet weet voordat **PANTOCID® 40 mg INJECTION** aan jou toegedien word
3. Hoe **PANTOCID® 40 mg INJECTION** toegedien word
4. Moontlike newe-effekte
5. Hoe om **PANTOCID® 40 mg INJECTION** te bewaar
6. Inhoud van die verpakking en ander inligting

1. WAT IS PANTOCID® 40 MG INJECTION EN WAARVOOR WORD DIT GEBRUIK

PANTOCID® 40 mg INJECTION bevat pantoprasool wat aan ‘n groep medisyne behoort wat bekend staan as protonpomp-remmers.

PANTOCID® 40 mg INJECTION word gebruik om sekere toestande te behandel waar daar te veel suur in die maag is. Dit word gebruik om duodenale en maagsere, refluks-esofagitis en Zollinger-Ellison-sindroom te behandel. **PANTOCID® 40 mg INJECTION** werk deur die hoeveelheid suur wat deur die maag geproduseer word, te verlaag.

2. **PANTOCID® 40 mg INJECTION** moet nie aan jou toegedien word nie**:**

- As jy hipersensitief (allergies) is vir pantoprasool of vir enige van die ander bestanddele van **PANTOCID® 40 mg INJECTION**.
- As jy ernstige lewerprobleme het.
- **PANTOCID® 40 mg INJECTION** moet nie aan kinders toegedien word nie.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgvoorsiener in voordat **PANTOCID® 40 mg INJECTION** aan jou toegedien word**:**

- Dat jy lewerprobleme het. Jou lewerensieme moet gedurende die behandeling gemoniteer word. **PANTOCID® 40 mg INJECTION** moet gestaak word in die geval van ‘n verhoging in lewerensieme.
- Dat jy ‘n maagseer of ‘n ernstige siekte van die esofagus het (die buis wat voedsel vanaf jou mond tot by jou maag vervoer).
- Dat jy teensuurmiddels oor ‘n lang tydperk gebruik het (d.i. langer as 3 jaar).
- Voortdurende behandeling met **PANTOCID® 40 mg INJECTION** kan lae serum-magnesiumvlakke veroorsaak met simptome soos moegheid, duiseligheid, ylhoofdigheid en konvulsies.
- Jou dokter sal **PANTOCID® 40 mg INJECTION** aan jou toedien, aangesien dit vir ‘n kort tydperk gebruik moet word, hoewel jou simptome mag voortduur ten spyte van jou behandeling. Jou dokter kan besluit dat sommige toetse uitgevoer moet word om die moontlikheid van kanker uit te skakel omdat **PANTOCID® 40 mg INJECTION** ook die simptome van kanker verlig en kan die oorsaak wees dat die diagnose daarvan vertraag word.
- Indien jy langtermyn-behandeling met **PANTOCID® 40 mg INJECTION** ontvang, is daar ‘n risiko van frakture van die heup, pols of ruggraat.
- Dat jy osteoporose het of as jy kortikosteroïede gebruik (wat die risiko van osteoporose kan verhoog).

- Dat jy ‘n spesifieke bloedtoets moet ondergaan wat chromogranien-A bepaal.

Ander medisyne en PANTOCID® 40 mg INJECTION:

Lig jou gesondheidsorgvoorsiener altyd in as jy ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in).

- **PANTOCID® 40 mg INJECTION** kan die absorpsie van sekere medisyne wat gebruik word om fungusinfeksies te behandel, soos ketokonasool en itrakonasool, verminder.
- **PANTOCID® 40 mg INJECTION** kan die hoeveelheid van atasanavir of nelfinavir wat gebruik word om MIV-infeksie te behandel, verminder.
- Medisyne wat jou bloed verdun, soos warfarien. **PANTOCID® 40 mg INJECTION** kan die effek van hierdie medisyne verander. Jou dokter sal monitor hoe goed jou bloed stol.
- **PANTOCID® 40 mg INJECTION** kan die vlakke van metotreksaat verhoog (hoë dosisse word gebruik in die behandeling van sekere kanker) en moontlik lei tot metotreksaat-vergiftiging.
- Fluvoksamien (wat gebruik word om depressie en ander psigiatriese siektes te behandel).
- Rifampisien (wat gebruik word om infeksies te behandel).
- Johanneskruid (*Hypericum perforatum*) (wat gebruik word om ligte depressie te behandel).

PANTOCID® 40 mg INJECTION saam met voedsel of drinkgoed

Voedsel affekteer nie die werking van **PANTOCID® 40 mg INJECTION** nie.

Swangerskap en borsvoeding:

As jy swanger is of borsvoed, dink dat jy swanger mag wees of van plan is om 'n baba te kry, raadpleeg jou dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat jy hierdie medisyne ontvang.

Veiligheid in swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en gebruik van masjinerie:

PANTOCID® 40 mg INJECTION kan duiseligheid en versteuring van visie (belemmerde visie) veroorsaak. Moenie ‘n voertuig bestuur of masjinerie hanteer nie totdat jy weet hoe **PANTOCID® 40 mg INJECTION** jou sal affekteer.

3. HOE OM PANTOCID® 40 MG INJECTION TE ONTVANG

Daar gaan nie van jou verwag word om **PANTOCID® 40 mg INJECTION** aan jouself toe te dien nie**.** Dit sal deur ‘n gekwalifiseeede persoon aan jou toegedien word. Jou dokter sal besluit op die geskikte dosis, gebaseer op jou toestand. Die normale dosis is 40 mg (een flessie).

As jy meer PANTOCID® 40 mg INJECTION ontvang het as wat jy behoort te ontvang:

Aangesien die gesondheidsorgvoorsiener **PANTOCID® 40 mg INJECTION** toedien, sal hy/sy die dosis beheer. In die geval van oordosering, sal jou dokter egter enige simptome van die oordosering hanteer.

4. MOONTLIKE NEWE-EFFEKTE

PANTOCID® 40 mg INJECTION kan newe-effekte hê. Nie alle newe-effekte wat vir hierdie medisyne aangemeld word, is in hierdie inligtingstuk opgeneem nie. Indien jou algemene gesondheid versleg terwyl jy hierdie medisyne ontvang, moet jy asseblief jou dokter, apteker of gesondheidsorgvoorsiener raadpleeg vir advies.

Indien enige van die volgende gebeur, moet die toediening van **PANTOCID® 40 mg INJECTION** gestaak word en jou dokter onmiddellik ingelig word of jy moet na die noodgevalle afdeling by jou naaste hospitaal gaan:

- swelling van die hande, voete, enkels, gesig, lippe, en mond, of keel, wat probleme met sluk of asemhaling kan veroorsaak,
- uitslag of gejeuk,
- floute.

Hierdie is almal baie ernstige newe-effekte. As jy hulle het, kon jy ‘n ernstige allergiese reaksie

teen **PANTOCID® 40 mg INJECTION** gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

Newe-effekte met 'n onbekende voorkoms:

- Ernstige velreaksies, soos Stevens-Johnson-sindroom, veelvuldige eriteem of Lyell-sindroom.
- Ontsteking van die nier (gekenmerk deur bloed in die urine, koors, verhoogde of verlaagde uitset van urine, lomerigheid, verwardheid, koma, naarheid, braking).
- Vergeling van die vel en oë (ook geelsug genoem).
- Lae vlakke van magnesium in jou liggaam met simptome soos moegheid, onwillekeurige spiersametrekkings, disoriëntasie, konvulsies, duiseligheid of 'n verhoogde hartritme.
- Verhoogde risiko vir gastro-intestinale infeksies, met gepaardgaande diarree.

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

Lig jou dokter so gou as moontlik in as jy enige van die volgende opmerk:

Newe-effekte wat algemeen voorkom:

- Klein groeiseltjies (poliepe) aan die binnewand van die maag.
- Pyn by die inspuitplek.

Newe-effekte wat minder algemeen voorkom:

- Bloedversteurings soos leukopenie ('n lae witbloedseltelling) of trombositopenie (verlaagde aantal plaatjies in die bloed).
- Verhoogde lewerensieme, trigliseriede ('n soort vet wat in jou bloed gevind word) of liggaamstemperatuur.
- Hoofpyn.
- Maagpyn,diarree, hardlywigheid, winderigheid.
- Bedrukte gevoel, slaapversteurings, disoriëntasie.
- Duiseligheid, belemmerde visie.
- Verdraaiing of totale verlies van jou smaaksensasie.

- Veranderinge in jou gewig.
- Droë mond.
- Opgeblasenheid, swelling van die maag.
- Veluitslag met rooi, opgehewe jeukerige knoppe, netelroos.
- Swelling van die hande, arms, bene en voete.
- Verhoogde liggaamstemperatuur.
- Naarheid (mislike gevoel), braking (gooi op), droë mond.
- Spier- of gewrigspyn.
- Vergroting van borste by mans en seuns (ginekomastie).
- Verlies aan energie of voel swak.
- Voel moeg.
- ‘n Algemene ongemaklike gevoel, siekte of ongemak waarvan dit moeilik is om die presiese oorsaak te bepaal.

Newe-effekte met ‘n onbekende voorkoms:

- ‘n Skielike verlies aan sig.
- Verwardheid, sien en hoor dinge wat nie bestaan nie.
- Naalde-en-spelde gevoel, branderige sensasie of dooie gevoel.
- Sensitiwiteit van jou vel wanneer aan sonlig blootgestel word.

Lig jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

Aanmelding van newe-effekte

Praat met jou dokter as jy newe-effekte ervaar. Jy kan ook newe-effekte aanmeld by SAHPRA *via* die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn onder SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **PANTOCID® 40 mg INJECTION** te verskaf**.**

5. HOE OM PANTOCID® 40 MG INJECTION TE BEWAAR

Bewaar by of onder 25 °C, beskerm teen lig.

Raak ontslae van enige ongebruikte oplossing.

Moenie **PANTOCID® 40 mg INJECTION** ná die vervaldatum soos op die etiket aangedui, ontvang nie.

Moenie van ongebruikte medisyne in dreinering- of riolerinstelsels (bv. toilette) ontslae raak nie.

BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat PANTOCID® 40 mg INJECTION bevat:

Aktiewe bestanddeel: Natriumpantoprasool-seskwihidraat.

Onaktiewe bestanddele: Water vir inspuiting, stikstof.

Hoe PANTOCID 40 MG INJECTION lyk en inhoud van die verpakking

PANTOCID® 40 mg INJECTION:

‘n Wit tot naaswit gevriesdroogde koekie in ‘n 10 mL kleurlose glasflessie vir intraveneuse inspuiting.

Die hersaamgestelde oplossing is ‘n helder, gelerige oplossing.

Een, vyf of tien flessies word in ‘n buitenste karton verpak.

Houer van die Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14, Stormill Uitbreiding 1

Roodepoort

Johannesburg 1724

011 495 0100

Hierdie inligtingstuk was laas hersien op

Each vial contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

12 Februarie 2024

Registrasienommer

PANTOCID® 40 mg INJECTION: A40/11.4.3/0072

Namibië:

PANTOCID® 40 mg INJECTION: NS2 Reg. nr.: 06/11.4.3/0332