SCHEDULING STATUS S4

PROPRIETARY NAME (AND DOSAGE FORM)
PANTOR 20 (enteric-coated tablet)
PANTOR 40 (enteric-coated tablet)

COMPOSITION
PANTOR 20: Each enteric-coated tablet contains:
Pantoprazole sodium sesquihydrate equivalent to pantoprazole 20 mg
Excipients: calcium stearate, crosspovidone, hydroxy propyl cellulose, hypromellose, mannitol, methacrylic acid ethyl acrylate co-polymer, propylene glycol, sodium carbonate anhydrous, talc, titanium dioxide, triethyl citrate, yellow oxide of iron.
PANTOR 40: Each enteric-coated tablet contains:
Pantoprazole sodium sesquihydrate equivalent to pantoprazole 40 mg
Excipients: calcium stearate, crosspovidone, hydroxy propyl cellulose, hypromellose, mannitol, methacrylic acid ethyl acrylate co-polymer, propylene glycol, sodium carbonate anhydrous, talc, titanium dioxide, triethyl citrate, yellow oxide of iron.

PHARMACOLOGICAL CLASSIFICATION
A.11.4.3 Medicines acting on the gastro-intestinal tract

PHARMACOLOGICAL ACTION
Pharmacodynamics
Pantoprazole is a proton pump inhibitor**,** i.e. it inhibits specifically and dose-proportionally H^+, K^+-ATPase, the enzyme, which is responsible for gastric acid secretion in the parietal cells of the stomach. Pantoprazole is a substituted benzimidazole, which accumulates in the acidic compartment of the parietal cells after absorption. In the parietal cell it is protonated and chemically re-arranged to the active inhibitor, a cyclic sulphonamide, which binds to the H^+, K^+-ATPase, thus inhibiting the proton pump and causing suppression of stimulated and basal gastric acid secretion after single and multiple intravenous and oral pantoprazole dosing. Because pantoprazole acts distal to the receptor level, it can influence gastric acid secretion irrespective of the nature of the stimulus.
Pantoprazole exerts its full effect in a strongly acidic environment pH < 3 and remains mostly inactive at higher pH values, which explains its selectivity for the acid secreting parietal cells of the stomach. Therefore, the complete pharmacological and therapeutic effect for pantoprazole can only be achieved in the acid-secreting parietal cells. By means of a feedback mechanism this effect is diminished at the same rate as acid secretion is inhibited.

Effect on gastric acid secretion
Following oral administration, pantoprazole inhibits the pentagastrin-stimulated gastric acid secretion. The mean acid inhibition was 85 %, 2½ to 3½ hours after dosing with 40 mg/day for 7 days.
Pantoprazole maintains the physiological pH-rhythm. The values, however, are shifted to higher levels. During the night, periods of pH values approximating placebo have been found to occur.
Although pantoprazole has a half-life of approximately 1 hour, the antisecretory effect increases during repeated once daily administration, demonstrating that the duration of action markedly exceeds the serum elimination half-life.

Pharmacokinetics
Absorption and distribution
Pantoprazole is unstable in acid and is administered orally in the form of an enteric-coated tablet.
Absorption takes place in the small intestine. On average, the maximum serum/plasma concentrations are approximately 2 to 3 µg/ml about 2,5 hours after administration of 40 mg pantoprazole daily, as a single or multiple dose in healthy volunteers. The absolute systemic bioavailability of pantoprazole from single and multiple oral doses of pantoprazole is approximately 77 %.
The plasma kinetics for pantoprazole after oral administration are linear over the dose range 10 - 80 mg.

Metabolism
Pantoprazole is almost exclusively metabolized in the liver. The main metabolite is desmethylpantoprazole, which is conjugated with sulphate.

Elimination
Renal elimination represents the most important route of excretion (approximately 80 %) for the metabolites of pantoprazole. The balance is excreted with the faeces.
The half-life of the main metabolite is approximately 1,5 hours, which is slightly longer than that of pantoprazole.
Pharmacokinetic profile in patients with impaired liver or renal function
For patients with mild to moderately severe hepatic cirrhosis the elimination half-life values increase to between 7 to 9 hours.
The AUC values increase by a factor of 5 to 8, while the maximum serum concentration only increases by a factor of 1,5 in comparison with healthy subjects.
In patients with renal impairment the half-life of the main metabolite is moderately increased**,** but there is not accumulation at therapeutic doses. The half-life of pantoprazole in patients with renal impairment is comparable to the half-life of pantoprazole in healthy subjects. Pantoprazole is poorly dialysed.
A slight increase in AUC and C_{max} occurs in elderly volunteers compared with younger people.

INDICATIONS
PANTOR 40 is indicated for the short-term treatment of duodenal ulcer, gastric ulcer and reflux oesophagitis. If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* infection, **PANTOR 40** used in combination with appropriate antibiotics may be useful.
PANTOR 40 is indicated for the treatment of Zollinger-Ellison Syndrome.
PANTOR 20 is indicated for the symptomatic improvement (e.g. heartburn, acid regurgitation, pain on swallowing) and healing of mild gastro-oesophageal reflux disease (GERD).
PANTOR 20 is indicated for long-term management and prevention of relapse in gastro-oesophageal reflux disease (GERD).

CONTRAINDICATIONS
Hypersensitivity to pantoprazole or any of the ingredients of **PANTOR.**
Safety and efficacy in children has not been established.
Concurrent use with atazanavir (See **INTERACTIONS**).
Severely impaired liver function (See **WARNINGS and SPECIAL PRECAUTIONS**).

WARNINGS and SPECIAL PRECAUTIONS
In patients with severe liver impairment the liver enzymes should be monitored regularly during treatment with **PANTOR**, particularly on long-term use. In the case of a rise of the liver enzymes **PANTOR** should be discontinued.
PANTOR is not indicated for mild gastro-intestinal complaints such as nervous dyspepsia.
Prior to treatment the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded, as the treatment with **PANTOR** may alleviate the symptoms of malignant ulcers and can thus delay diagnosis.
Diagnosis of reflux oesophagitis should be confirmed by endoscopy.
Daily treatment with any acid-blocking medicines over a long period of time (e.g. longer than 3 years) may lead to malabsorption of cyanocobalamin caused by hypo- or achlorhydria. Rare cases of cyanocobalamin deficiency under acid-blocking therapy have been reported in the literature. This should be considered when respective clinical symptoms are observed.

INTERACTIONS
Concomitant intake of food has no influence on the bioavailability.
PANTOR may reduce or increase the absorption of medicines whose absorption is pH dependent, e.g. ketoconazole.
Atazanavir: it has been shown that co-administration of atazanavir/ritonavir with omeprazole or atazanavir with lansoprazole resulted in a substantial reduction in the bioavailability of atazanavir. The absorption of atazanavir is pH dependent. Therefore, pantoprazole must not be co-administered with atazanavir (see **CONTRA-INDICATIONS**).
The active ingredient of **PANTOR** is metabolized in the liver via the cytochrome P450 enzyme system. An interaction of **PANTOR** with other medicines or compounds, which are metabolized using the same enzyme system, cannot be excluded.
No clinically significant interactions were, however, observed in specific tests with a number of such medicines or compounds, namely antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, naproxen, nifedipine, phenytoin, piroxicam, theophylline, warfarin and oral contraceptives. However, the response to anti-coagulants, such as warfarin, may be affected by any concomitant medication. Therefore, monitoring the patient with additional PT (prothrombin time) / INR (International normalised ratio) determinations when **PANTOR** is initiated, discontinued or taken irregularly would be a good practice.
There were no interactions with concomitantly administered antacids.

PREGNANCY AND LACTATION
Safety in pregnancy and during lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
The recommended once daily dose of **PANTOR** should be taken in the morning. **PANTOR** should be swallowed whole with a little water either before or during breakfast.
Duodenal ulcer
The recommended oral dose is 40 mg of **PANTOR** once daily. The total treatment with pantoprazole should be 2 to 4 weeks. If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* infection 40 mg of **PANTOR** used in combination with appropriate antibiotics may be useful.
Gastric ulcer
The recommended oral dose is 40 mg of **PANTOR** once daily for 4 to 8 weeks.
In the case of a suspected gastric ulcer, malignancy of the gastric ulcer should be excluded, as treatment could conceal the symptoms and may delay diagnosis.
Reflux oesophagitis
The recommended oral dose is 40 mg of **PANTOR** once daily in the morning for 4 to 8 weeks.
Zollinger-Ellison Syndrome
For the management of Zollinger-Ellison Syndrome patients should start their treatment with a daily dose of 80 mg of **PANTOR** (two **PANTOR** 40 tablets)**.**
Thereafter, the dosage can be titrated up or down as needed using measurements of gastric acid secretion as a guide. With doses above 80 mg daily, the dose should be divided and given twice daily.
Mild Gastro-oesophageal reflux disease (GERD)
The recommended oral dose is 20 mg of **PANTOR** per day. A 4-week period is usually required for healing of mild GERD. If this is not sufficient, healing will usually be achieved within a further 4 weeks.
Long-term management and prevention of relapse in GERD
For long-term management a maintenance dose of one 20 mg **PANTOR** tablet per day is recommended, increasing to 40 mg **PANTOR** per day if a relapse occurs. After healing of the relapse, the dose can be reduced to 20 mg of **PANTOR**. Experience with long-term administration is limited.
Elderly patients
No dosage adjustment is necessary in the elderly.
Impaired renal and liver function
No dosage adjustment is required in the presence of impaired renal function.
A daily dose of 20 mg of **PANTOR** should not be exceeded in patients with mild to moderately severe liver impairment (see **Pharmacokinetics** and **WARNINGS and SPECIAL PRECAUTIONS**).

SIDE-EFFECTS
Blood and lymphatic system
Less frequent: Leukopenia, thrombocytopenia.
Gastro-intestinal disorders
Frequent: Gastro-intestinal complaints such as upper abdominal pain, diarrhoea, constipation or flatulence.
Less frequent: Nausea, vomiting, dry mouth.
Hepatobiliary disorders
Less frequent: Severe hepatocellular damage leading to jaundice with or without hepatic failure.
Immune system disorders
Less frequent: Anaphylactic reactions including anaphylactic shock.
Metabolic disorders
Less frequent: Increased liver enzymes (transaminases, γ-GT), elevated triglycerides and increased body temperature.
Musculoskeletal, connective tissue and bone disorders
Less frequent*:* Arthralgia, myalgia.
Nervous System disorders
Frequent*:* Headache.
Less frequent*:* Dizziness or disturbances in vision (blurred vision).
Psychiatric disorders
Less frequent*:* Mental depression.
Renal and urinary system disorders
Less frequent*:* Interstitial nephritis.
Skin and subcutaneous tissue disorders
Less frequent*:* Allergic reactions such as pruritus, and skin rash**,** urticaria, angioedema and severe skin reactions such as Stevens-Johnson Syndrome, erythema multiforme, Lyell Syndrome and photosensitivity.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
There are no known symptoms of overdosage in man. No specific therapeutic recommendation can be made in cases of overdosage. Treatment is symptomatic and supportive.

IDENTIFICATION
PANTOR 20: 8,9 mm long and 3,6 mm thick, yellow coloured, oval shaped, biconvex, enteric-coated tablets, plain on both sides.
PANTOR 40: 11,7 mm long and 4,4 mm thick, yellow coloured, oval shaped, biconvex, enteric-coated tablets, plain on both sides.

PRESENTATION
PANTOR 20: 30's (3 x 10's) in Alu/Alu blister strips.
PANTOR 40: 30's (3 x 10's) in Alu/Alu blister strips.

STORAGE INSTRUCTIONS
Store at or below 25 °C in a dry place and protected from light.
Keep blistered tablets in blister pack and box until a dose must be taken.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS
PANTOR 20: 43/11.4.3/0696
PANTOR 40: 43/11.4.3/0697

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Trinity Pharma (Pty) Ltd.
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MANUFACTURER
Torrent Pharmaceuticals Limited, Gujarat, India.

DATE OF PUBLICATION OF THIS PACKAGE INSERT
20 June 2013

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
PANTOR 20 enteric-coated tablet
PANTOR 40 enteric-coated tablet

Read all of this leaflet carefully before you start taking PANTOR
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **PANTOR** 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 PANTOR CONTAINS
PANTOR 20: Each enteric-coated tablet contains:
Pantoprazole sodium sesquihydrate equivalent to pantoprazole 20 mg
The other ingredients are mannitol, crosspovidone, sodium carbonate anhydrous, hydroxy propyl cellulose, calcium stearate, hypromellose, titanium dioxide, yellow oxide of iron, propylene glycol, methacrylic acid ethyl acrylate co-polymer, triethyl citrate, talc.
PANTOR 40: Each enteric-coated tablet contains:
Pantoprazole sodium sesquihydrate equivalent to pantoprazole 40 mg
The other ingredients are mannitol, crosspovidone, sodium carbonate anhydrous, hydroxy propyl cellulose, calcium stearate, hypromellose, titanium dioxide, yellow oxide of iron, propylene glycol, methacrylic acid ethyl acrylate co-polymer, triethyl citrate, talc.

WHAT PANTOR IS USED FOR
PANTOR belongs to a group of medicines called proton pump inhibitors. It works in the stomach by blocking the 'pump' that produces the acid. Hence it reduces the amount of acid in the stomach.
PANTOR is used for:
- treatment of mild gastro-oesophageal reflux disease (GERD) and associated symptoms (e.g. heartburn, sour taste in the mouth, pain on swallowing). Reflux is the backflow of acid from the stomach into the gullet ("food pipe"), which may become inflamed and painful.
- for the long-term treatment and prevention of recurrent reflux oesophagitis (inflammation of the gullet).
- for short term treatment of stomach (gastric) ulcer.
- for treatment of an illness known as Zollinger-Ellison Syndrome.

BEFORE YOU TAKE PANTOR
Do not use **PANTOR** under the following conditions:
- Hypersensitivity to pantoprazole or any of the ingredients of **PANTOR**.
- Safety and efficacy in children has not been established.
- Severely impaired liver function.
- Mild gastro-intestinal complaints such as nervous dyspepsia.
- If you are taking atazanavir (a medicine used to treat HIV infections).

Take special care with **PANTOR**
- if you suffer from severe liver problems or jaundice (yellowing of the eyes and skin) please tell your doctor who will decide whether your dose has to be adjusted.
- if you ever had a deficiency of vitamin B12, please tell your doctor who might then check for your vitamin B12 levels.
- inform your doctor if you have been treated for heartburn or indigestion continuously for 4 or more weeks.

Tell your doctor immediately before or while taking **PANTOR**
- if you experience unintentional weight loss, unrelated to dieting or exercise programme.
- if you suffer from recurrent vomiting, pain on swallowing or vomiting of blood.
- if you have experienced blood in your stool or very dark stools.
- if you experience severe and/or persistent diarrhoea, because **PANTOR** has been associated with a small increase in infectious diarrhoea.

Your doctor might possibly perform some tests.
Please also tell your doctor if your symptoms persist despite adequate treatment with **PANTOR**.

Taking other medicines with PANTOR
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **PANTOR** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.
Please tell your doctor or pharmacist if you are taking any of the following medicines:
- Medicines to thin your blood (e.g. warfarin). Your doctor will need to monitor clotting properties of your blood.
- Medicines to treat fungal infections (e.g. ketoconazole or itraconazole).
- Atazanavir for the treatment of HIV infection, which you must not take together with **PANTOR.**

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby while taking **PANTOR**, please consult your doctor, pharmacist or other health care professional for advice before using this medicine.

Driving and using machinery
PANTOR is not known to affect your ability to drive or operate machines.

HOW TO TAKE PANTOR
Do not share medicines prescribed for you with any other person.
Your doctor will decide on the correct dose of **PANTOR** for you and this will depend on which condition or illness you are being treated for.

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

The recommended once daily dose of **PANTOR** should be taken in the morning. **PANTOR** should be swallowed whole with a little water either before or during breakfast.

Duodenal ulcer
The recommended oral dose is 40 mg of **PANTOR** once daily for 2 to 4 weeks.

Gastric ulcer
The recommended oral dose is 40 mg of **PANTOR** once daily for 4 to 8 weeks.

Reflux oesophagitis
The recommended oral dose is 40 mg of **PANTOR** once daily in the morning for 4 to 8 weeks.

Zollinger- Ellison Syndrome
The usual starting is 80 mg (two 40 mg tablets) of **PANTOR** per day. The dose may be increased or decreased by your doctor as needed, using the results of test to measure the amount of acid in the stomach as a guide. Where the dose is increased to more than 80 mg per day, your doctor will advise you to take the medicine twice a day.

Mild Gastro-oesophageal reflux disease (GERD)
The recommended oral dose is 20 mg of **PANTOR** per day. A 4-week period is usually required for healing of mild GERD. If this is not sufficient, healing will usually be achieved within a further 4 weeks.

Long-term management and prevention of recurrent GERD
The usual dose for long-term treatment is 20 mg of **PANTOR** per day.
If GERD recurs or the symptoms worsen while taking a daily dose of 20 mg of **PANTOR** per day, your doctor may increase the dose to 40 mg of **PANTOR** per day.
Once healing has been achieved the doctor will once more reduce the dose to 20 mg of **PANTOR.**

Elderly patients
No dosage adjustment is necessary in the elderly.

Impaired kidney and liver function
No dosage adjustment is required in the presence of impaired kidney function.
A daily dose of 20 mg of **PANTOR** should not be exceeded in patients with mild to moderately severe liver impairment.

If you take more PANTOR than you should
In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital. Always take the tablets and carton with you to the hospital so that the doctor knows what has been taken.

If you forget to take PANTOR
If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten doses.

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

Tell your doctor immediately if:
- you notice a soreness in your mouth and throat, skin reactions with blistering or ulceration, swelling of the mouth, lips or tongue, or if you experience increased pulse rate or increased sweating.
- rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash when exposed to the sun.
- your skin or whites of your eyes become more yellow than normal.
- or kidney problems such as painful urination and lower back pain with fever.

Other side effects may include:
Frequent: Headache, constipation, wind, stomach pain and diarrhoea.
Less Frequent: Skin rash, itchiness, nausea, vomiting, dizziness or blurred vision, dry mouth, muscle pain and joint pain.

STORING AND DISPOSING OF PANTOR
Store all medicines out of reach of children.
Store at or below 25 °C in a dry place and protected from light.
Keep blistered tablets in blister pack and box until a dose must be taken.
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).

PRESENTATION OF PANTOR
PANTOR 20: 30's (3 x 10's) in Alu/Alu blister strips.
PANTOR 40: 30's (3 x 10's) in Alu/Alu blister strips.

IDENTIFICATION OF PANTOR
PANTOR 20: 8,9 mm x 3,6 mm, yellow coloured, oval shaped, biconvex, enteric-coated tablets, plain on both sides.
PANTOR 40: 11,7 mm x 4,4 mm, yellow coloured, oval shaped, biconvex, enteric-coated tablets, plain on both sides.

REGISTRATION NUMBER:
PANTOR 20: 43/11.4.3/0696
PANTOR 40: 43/11.4.3/0697

NAME AND ADDRESS OF REGISTRATION HOLDER
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MANUFACTURER
Torrent Pharmaceuticals Limited, Gujarat, India.

DATE OF PUBLICATION
20 June 2013

Namibia NS2
PANTOR 20: 16/11.4.3/0004
PANTOR 40: 16/11.4.3/0005

SKEDULERINGSTATUS S4

HANDELSNAAM (EN DOSEERVORM)
PANTOR 20 (enteries-bedekte tablet)
PANTOR 40 (enteries-bedekte tablet)

SAMESTELLING
PANTOR 20: Elke enteries-bedekte tablet bevat:
Pantoprasoolnatrium seskwihidraat ekwivalent aan pantoprasool 20 mg.
Mengmiddels: kalsiumstearaat, krospovidoon, hidroksipropiel-sellulose, hipromellose, mannitol, metakrielsuur etielakrilaat kopolimeer, propileenglikol, natriumkarbonaat anhidries, talk, titaandioksied, triëtielsitraat, geel ysteroksied.
PANTOR 40: Elke enteries-bedekte tablet bevat:
Pantoprasoolnatrium seskwihidraat ekwivalent aan pantoprasool 40 mg.
Mengmiddels: kalsiumstearaat, krospovidoon, hidroksipropiel-sellulose, hipromellose, mannitol, metakrielsuur etielakrilaat kopolimeer, propileenglikol, natriumkarbonaat anhidries, talk, titaandioksied, triëtielsitraat, geel ysteroksied.

FARMAKOLOGIESE KLASSIFIKASIE
A.11.4.3 Medisyne wat op die spysverteringskanaal werk.

FARMAKOLOGIESE WERKING
Farmakodinamika
Pantoprasool is 'n protonpompinhibeerder, d.i. dit inhibeer, spesifiek en dosis-proporsioneel H^+, K^+ -ATPase, die ensiem wat verantwoordelik is vir maagsuursekresie in die pariëtale selle van die maag. Pantoprasool is 'n gesubstitueerde bensimidasool, wat in die suur kompartement van die pariëtale selle akkumuleer na absorpsie. Dit word in die pariëtale sel geprotoneer en chemies hergerangskik om die aktiewe inhibeerder, 'n sikliese sulfonamied, te vorm, wat aan die H^+, K^+ -ATPase bind, en dus die protonpomp inhibeer en onderdrukking veroorsaak van die gestimuleerde en basale sekresie van maagsuur na enkele en veelvoudige intraveneuse en orale pantoprasooldosering. Omdat pantoprasool distaal tot die reseptorvlak werk, kan dit maagsuursekresie beïnvloed ongeag die aard van die stimulus.
Pantoprasool oefen sy volle effek uit in 'n sterk suur omgewing pH < 3, en is meestal onaktief by hoër pH-waardes, wat sy selektiwiteit vir die pariëtale selle van die maag wat suur afskei, verduidelik. Die volledige farmakologiese en terapeutiese effek van pantoprasool kan dus slegs bereik word in die pariëtale selle wat suur afskei. Deur middel van 'n terugvoermeganisme word hierdie effek verminder teen dieselfde tempo waarteen die suurafsekiding geïnhibeer word.

Effek op maagsuursekresie
Na orale toediening inhibeer pantoprasool pentagastrien-stimulerende maagsuursekresie. Die gemiddelde suurinhibisie was 85 %, 2½ tot 3½ uur na dosering met 40 mg/dag vir 7 dae.
Pantoprasool onderhou die fisiologiese pH-ritme. Die waardes word egter na hoër vlakke verskuif. Tydens die nag, is daar gevind dat periodes van pH-waardes wat plasebo approksimeer, wel voorkom.
Alhoewel pantoprasool 'n halfleeftyd van ongeveer 1 uur het, word die anti-sekretoriese effek verhoog deur herhaalde een keer daaglikse toediening, wat demonstreer dat die duur van werking die serum eliminasie halfleeftyd aansienlik oortref.

Farmakokinetika
Absorpsie en distribusie
Pantoprasool is onstabiel in suur en word per mond in die vorm van 'n enteries-bedekte tablet toegedien.
Absorpsie vind in die dunderm plaas. Gemiddeld is die maksimum serum-/plasmakonsentrasies ongeveer 2 tot 3 µg/ml omtrent 2,5 uur na toediening van 40 mg pantoprasool daagliks, as 'n enkele of veelvoudige dosis in gesonde vrywilligers. Die absolute sistemiese biobeskikbaarheid van pantoprasool van enkele en veelvoudige orale dosisse pantoprasool is ongeveer 77 %.
Die plasma kinetika vir pantoprasool na orale toediening is liniër oor die dosisreikwydte van 10-80 mg.

Metabolisme
Pantoprasool word amper eksklusief in die lewer gemetaboliseer. Die hoofmetaboliet is desmetielpantoprasool, wat met sulfaat gekonjugeer is.

Eliminasie
Renale eliminasie verteenwoordig die mees belangrike roete vir uitskeiding (ongeveer 80 %) vir die metaboliete van pantoprasool. Die balanse word saam met die feses uitgeskei. Die halfleeftyd van die hoofmetaboliet is ongeveer 1,5 uur, wat effens langer is as dié van pantoprasool.

Farmakokinetiese profiel by pasiënte met ingekorte lewer- of nierfunksie
Vir pasiënte met lig tot matig ernstige hepatiese sirrose verhoog die eliminasie halfleeftyd waardes tot tussen 7 tot 9 uur.
Die AOK-waardes verhoog met 'n faktor van 5 tot 8, terwyl die maksimum serumkonsentrasie slegs met 'n faktor van 1,5 verhoog in vergelyking met gesonde proefpersone. By pasiënte met nierinkorting is die halfleeftyd van die hoofmetaboliet matig verhoog, maar geen akkumulasie vind by terapeutiese dosisse plaas nie. Die halfleeftyd van pantoprasool by pasiënte met nierinkorting is vergelykbaar met die halfleeftyd van pantoprasool in gesonde persone. Pantoprasool word swak gedialiseer.
'n Effense verhoging in AOK en K_{maks} kom by bejaarde vrywilligers in vergelyking met jonger mense voor.

INDIKASIES
PANTOR 40 word vir die kort-termyn behandeling van duodenale ulkus, gastriese ulkus en refluks-esofagitis aangedui. Indien daar aangedui kon word dat die duodenale ulkus met *Helicobacter pylori* infeksie geassosieer is, mag **PANTOR 40** wat in kombinasie met toepaslike antibiotika gebruik word, van waarde wees.
PANTOR 40 word aangedui vir die behandeling van Zollinger-Ellison-Sindroom.
PANTOR 20 word aangedui vir die simptomatiese verbetering (bv. sooibrand, suur regurgitasie, pyn met sluk) en genesing van ligte gastroësofageale refluksiekte (GERD).
PANTOR 20 word aangedui vir die langtermyn beheer en voorkoming van terugval in gastroësofageale reflukssiekte (GERD).

KONTRA-INDIKASIES
Hipersensitiwiteit teen pantoprasool of enige van die bestanddele van **PANTOR**.
Veiligheid en doeltreffendheid by kinders is nie vasgestel nie.
Gelyktydige gebruik saam met atasanavir (Sien **INTERAKSIES**).
Ernstig ingekorte lewerfunksie (Sien **WAARSKUWINGS en SPESIALE VOORSORGMAATREELS**)

WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS
In pasiënte met ernstige lewerinkorting, behoort die lewerensieme gereeld tydens behandeling met **PANTOR** gemoniteer te word, veral tydens langtermyn gebruik. In die geval van 'n verhoging in lewerensieme, behoort **PANTOR** gestaak te word.
PANTOR word nie vir ligte gastroïntestinale klagtes soos senuagtige dispepsie aangedui nie.
Voor behandeling moet die moontlikheid van die kwaadaardigheid van 'n gastriese ulkus of 'n kwaadaardige siekte van die esofagus uitgesluit word, omdat die behandeling die simptome van kwaadaardige ulkusse mag verlig en diagnose dus mag vertraag.
Diagnose van refluks-esofagitis behoort met endoskopie bevestig te word.
Daaglikse behandeling met enige suur-blokkerende medisyne oor 'n lang periode van tyd (bv. langer as 3 jaar) mag lei tot wanabsorpsie van sianokobalamien wat deur hipo- of achlorhidrie veroorsaak word. Seldsame gevalle van 'n sianokobalamiengebrek tydens suur-blokkeringsterapie is al in die literatuur gerapporteer. Dit behoort in ag geneem te word wanneer respektiewe kliniese simptome waargeneem word.

INTERAKSIES
Gelyktydige inname van kos het geen invloed op die biobeskikbaarheid nie.
PANTOR mag die absorpsie van medisyne by wie die absorpsie pH-afhanklik is, bv. ketokonasool, verminder of verhoog.
Atasanavir: daar kon aangedui word dat die gelyktydige toediening van atasanavir/ritonavir saam met omeprasool of atasanavir met lansoprasool 'n aansienlike verlaging van die biobeskikbaarheid van atasanavir veroorsaak het. Die absorpsie van atasanavir is pH-afhanklik. Pantoprasool moet dus nie saam met atasanavir toegedien word nie (sien **KONTRA-INDIKASIES**).
Die aktiewe bestanddeel van **PANTOR** word in die lewer deur die sitochroom P450 ensiemsisteem gemetaboliseer. 'n Interaksie van **PANTOR** met ander medisyne of verbindings, wat gemetaboliseer word deur van dieselfde ensiemsisteem gebruik te maak, kan nie uitgesluit word nie.
Geen klinies beduidende interaksies is egter in spesifieke toetse met 'n aantal van sulke medisyne of verbindings waargeneem nie, naamlik antipirien, kafeïen, karbamasepien, diasepam, diklofenak, digoksien, etanol, glibenklamied, metoprolol, naproksen, nifedipien, fenitoïen, piroksikam, teofillien, warfarien, en orale kontraseptiewe.
Die reaksie op antikoagulante soos warfarien mag egter deur enige gelyktydige medikasie geaffekteer word. Monitering van die pasiënt met addisionele PT-bepalings (protrombientyd)/INR (Internasionale genormaliseerde verhouding) wanneer **PANTOR** begin, gestaak of ongereeld geneem word, sal as goeie praktyk beskou word.
Geen interaksies met gelyktydig toegediende teensuurmiddels het voorgekom nie.

SWANGERSKAP EN LAKTASIE
Veiligheid in swangerskap en tydens laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS
Die aanbevole een keer daaglikse dosis **PANTOR** behoort in die oggend geneem te word. **PANTOR** behoort heel ingesluk te word saam met 'n bietjie water voor of gedurende ontbyt.
Duodenale ulkus
Die aanbevole orale dosis is 40 mg **PANTOR** een keer daagliks. Die totale behandeling met pantoprasool behoort 2 tot 4 weke in beslag te neem. Indien daar aangedui kon word dat die duodenale ulkus met *Helicobacter pylori* infeksie geassosieer is, mag **40 mg PANTOR** wat in kombinasie met toepaslike antibiotika gebruik word, van waarde wees.
Gastriese ulkus
Die aanbevole orale dosis is 40 mg **PANTOR** een keer daagliks vir 4 tot 8 weke. In 'n geval van 'n vermoede gastriese ulkus, moet kwaadaardigheid van die gastriese ulkus uitgesluit word, omdat behandeling moontlik die simptome mag verberg en dus die diagnose mag vertraag.
Refluks-esofagitis
Die aanbevole orale dosis is 40 mg **PANTOR** een keer daagliks in die oggend vir 4 tot 8 weke.
Zollinger-Ellison-Sindroom
Vir die hantering van Zollinger-Ellison-Sindroom behoort pasiënte hul behandeling met 'n daaglikse dosis van 80 mg **PANTOR** (twee **PANTOR** 40 tablette) te begin.
Daarna kan die dosering soos nodig op of af getitreer word deur van bepalings van maagsuursekresie as riglyn gebruik te maak. Met dosisse bo 80 mg daagliks, behoort die dosis verdeel te word en twee keer daagliks gegee te word.
Ligte Gastroësofageale refluksiekte (GERD)
Die aanbevole orale dosis is 20 mg **PANTOR** per dag. 'n 4-week periode is gewoonlik nodig vir die genesing van ligte GERD. Indien dit onvoldoende is, sal genesing gewoonlik binne 'n addisionele 4 weke bereik word.
Langtermyn hantering en voorkoming van terugval in GERD:
Vir langtermyn hantering word 'n onderhoudsdosis van een 20 mg **PANTOR** tablet per dag aanbeveel, met 'n verhoging tot 40 mg **PANTOR** per dag indien 'n terugval sou voorkom. Na genesing van die terugval, kan die dosis weer verminder word tot 20 mg **PANTOR**. Ondervinding met langtermyn toediening is beperk.
Bejaarde pasiënte
Geen dosisaanpassing is by bejaardes nodig nie.
Ingekorte nier- en lewerfunksie
Geen dosisaanpassing is in die teenwoordigheid van ingekorte nierfunksie nodig nie.
'n Daaglikse dosis van 20 mg **PANTOR** behoort nie by pasiënte met lig tot matig ernstige lewerinkorting oorskry te word nie (sien **Farmakokinetika** en **WAARSKUWINGS en SPESIALE VOORSORGMAATREELS**).

NEWE-EFFEKTE
Bloed- en limfatiese sisteem
Minder frekwent: Leukopenie, trombositopenie.
Gastroïntestinale versteurings
Frekwent: Gastroïntestinale klagtes soos pyn in die boonste deel van die buik, diarree, hardlywigheid of winderigheid.
Minder frekwent: Naarheid, braking, droë mond.
Hepatobiliêre versteurings
Minder frekwent: Ernstige hepatosellulêre skade wat tot geelsug met, of sonder lewerversaking lei.
Immuunsisteemversteurings
Minder frekwent: Anafilaktiese reaksies insluitend anafilaktiese skok.
Metaboliese versteurings
Minder frekwent: Verhoogde lewerensieme (transaminases (γ-GT), verhoogde trigliseriede en verhoogde liggaamstemperatuur.
Muskuloskeletale, bindweefsel- en beënversteurings
Minder frekwent: Artralgie, mialgie.
Senusisteemversteurings
Frekwent: Hoofpyn.
Minder frekwent: Duiseligheid of versteurde visies (belemmerde visie).
Psigiatriese versteurings
Minder frekwent: Geestesdepressie.
Renale en urinêre sisteemversteurings
Minder frekwent: Interstisiële nefritis.
Vel- en onderhuidse weefselversteurings
Minder frekwent: Allergiese reaksies soos pruritus en veluitslag, urtikarie, angio-edeem en ernstige velreaksies soos Stevens-Johnson-Sindroom, erythema multiforme, Lyell se Sindroom en fotosensitiwiteit.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Daar is geen simptome van oordosering by die mens bekend nie. Geen spesifieke terapeutiese aanbeveling kan in gevalle van oordosering gemaak word nie. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
PANTOR 20: 8,9 mm lank en 3,6 mm dik, geelkleurige, ovaalvormige, bikonvekse, enteries-bedekte tablette sonder versiering op albei kante.
PANTOR 40: 11,7 mm lank en 4,4 mm dik, geelkleurige, ovaalvormige, bikonvekse, enteries-bedekte tablette sonder versiering op albei kante.

AANBIEDING
PANTOR 20: 30s (3 x 10) in Alu/Alu stolpverpakkingstroke.
PANTOR 40: 30s (3 x 10) in Alu/Alu stolpverpakkingstroke.

BERGINGSAANWYSINGS
Berg teen of benede 25 ºC in 'n droë plek, en beskerm teen lig.
Hou die verpakte tablette in hul stolpverpakkings en karton totdat 'n dosis geneem moet word.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS
PANTOR 20: 43/11.4.3/0696
PANTOR 40: 43/11.4.3/0697

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VERVAARDIGER
Torrent Pharmaceuticals Limited, Gujarat, India.

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20 Junie 2013

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
PANTOR 20 enteries-bedekte tablet
PANTOR 40 enteries-bedekte tablet

Lees hierdie hele brosjure versigtig voordat jy begin om PANTOR te gebruik
- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker.
- **PANTOR** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander persone te deel nie. Dit kan hulle skade aandoen, selfs al is hulle simptome dieselfde as joune.

WAT PANTOR BEVAT
PANTOR 20: Elke enteries-bedekte tablet bevat:
Pantoprasoolnatrium seskwihidraat ekwivalent aan pantoprasool 20 mg.
Mengmiddels: mannitol, krospovidoon, natriumkarbonaat anhidries, hidroksipropielsellulose, kalsiumstearaat, hipromellose, titaandioksied, geel ysteroksied, propileenglikol, metakrielsuur etielakrilaat kopolimeer, triëtielsitraat, talk.
PANTOR 40: Elke enteries-bedekte tablet bevat:
Pantoprasoolnatrium seskwihidraat ekwivalent aan pantoprasool 40 mg.
Mengmiddels: mannitol, krospovidoon, natriumkarbonaat anhidries, hidroksipropielsellulose, kalsiumstearaat, hipromellose, titaandioksied, geel ysteroksied, propileenglikol, metakrielsuur etielakrilaat kopolimeer, triëtielsitraat, talk.

WAARVOOR PANTOR GEBRUIK WORD
PANTOR behoort aan die groep medisyne wat protonpompinhibeerders genoem word. Dit werk in die maag deurdat dit die 'pomp' blokkeer wat die suur produseer. Gevolglik verminder dit die hoeveelheid suur in die maag.

PANTOR word gebruik vir
- behandeling van ligte gastroësofageale reflukssiekte (GERD) en geassosieerde simptome (bv. sooibrand, suur smaak in die mond, pyn met sluk). Refluks is die terugvloei van suur van die maag in die esofagus ("slukderm"), wat inflammasie van ontwikkel en pynlik word.
- vir die langtermyn behandeling en voorkoming van herhalende refluks-esofagitis (inflammasie van die slukderm).
- vir die kort-termyn behandeling van maag (gastriese) ulkus.
- vir die behandeling van 'n siekte wat as Zollinger-Ellison-Sindroom bekend staan.

VOORDAT JY PANTOR NEEM
Moenie **PANTOR** in die volgende toestande gebruik nie:
- Hipersensitiwiteit teen pantoprasool of enige van die bestanddele van **PANTOR.**
- Veiligheid en doeltreffendheid by kinders is nie vasgestel nie.
- Ernstig ingekorte lewerfunksie.
- Ligte gastroïntestinale klagtes soos senuagtige dispepsie.
- Indien jy atasanavir ('n medisyne wat gebruik word om MIV-infeksies te behandel) neem.

Neem spesiale sorg met **PANTOR**
- indien jy ly aan ernstige lewerprobleme of geelsug (vergeling van die oë en vel), moet jy asseblief jou dokter daarvan vertel. Hy/sy sal besluit of jou dosis aangepas moet word.
- indien jy al ooit 'n gebrek aan vitamien B12 gehad het, moet jy asseblief jou dokter daarvan vertel. Hy/sy sal dan moontlik jou vitamien B12-vlakke laat bepaal.
- vertel jou dokter indien jy vir sooibrand of indigestie aanhoudend vir 4 of meer weke behandel is.

Vertel jou dokter dadelik voor of terwyl jy **PANTOR** neem
- indien jy enige onbedoelde gewigsverlies ondervind wat nie aan 'n verslankingsdieet of oefenprogram verwant is nie.
- indien jy aan herhaalde braking pyn met sluk of braak van bloed ly.
- indien jy bloed in jou stoelgang of baie donker stoelgang ondervind het.
- indien jy ernstige en/of aanhoudende diarree ondervind, omdat **s** al met 'n klein toename in infektiewe diarree, geassosieer is.

Jou dokter sal moontlik 'n paar toetse laat doen.
Vertel ook jou dokter indien jou simptome voortduur ten spyte van toereikende behandeling met **PANTOR**.

Neem van ander medisyne saam met PANTOR
Indien jy ander medisyne gereeld neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van **PANTOR** saam met hierdie medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies.

Vertel asseblief jou dokter of apteker indien jy enige van die volgende medisyne neem:
- Medisyne om jou bloed te verdun (bv. warfarien). Jou dokter sal die stollingseienskappe van jou bloed moet moniteer.
- Medisyne om swaminfeksies te behandel (bv. ketokonasool of itrakonasool).
- Atasanavir vir die behandeling van MIV-infeksie, wat jy nie saam met **PANTOR** moet neem nie.

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, terwyl jy **PANTOR** neem, moet jy asseblief jou dokter, apteker of gesondheidsorgdeskundige vir advies raadpleeg voordat jy hierdie medisyne gebruik.
Bestuur en gebruik van masjiene
PANTOR is nie daarvoor bekend dat dit jou vermoë om te bestuur of masjiene te gebruik, sal affekteer nie.

HOE OM PANTOR TE NEEM
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Jou dokter sal besluit oor die korrekte dosis **PANTOR** wat sal afhang vir watter toestand of siekte jy behandel word.

Indien jy onder die indruk verkeer dat die effek van **PANTOR** te sterk of te swak is, gesels met jou dokter of apteker daaroor.

Die aanbevole een-keer-daaglikse dosis **PANTOR** moet in die oggend geneem word. **PANTOR** moet heel ingesluk word saam met 'n bietjie water voor of tydens ontbyt.

Duodenale ulkus:
Die aanbevole mondelinge dosis is 40 mg **PANTOR** een keer daagliks vir 2 tot 4 weke.
Gastriese ulkus:
Die aanbevole mondelinge dosis is 40 mg **PANTOR** een keer daagliks vir 4 tot 8 weke.
Refluks-esofagitis:
Die aanbevole mondelinge dosis is 40 mg **PANTOR** een keer daagliks vir 4 tot 8 weke.
Zollinger-Ellison-Sindroom:
Die gebruiklike aanvangsdosis is 80 mg(twee 40 mg tablette) **PANTOR** per dag.
Die dosis kan deur jou dokter soos nodig verhoog of verlaag word, deur die resultate van toetse om die hoeveelheid suur in die maag te meet, as riglyn te gebruik.
Waar die dosis tot meer as 80 mg per dag verhoog is, sal jou dokter vir jou aanraai om die medisyne twee keer per dag te neem.
Ligte Gastroësofageale reflukssiekte (GERD):
Die aanbevole mondelinge dosis is 20 mg **PANTOR** per dag. 'n 4-week periode is gewoonlik nodig vir die genesing van ligte GERD. Indien dit onvoldoende is, sal genesing gewoonlik binne 'n addisionele 4 weke bereik word.
Langtermyn hantering en voorkoming van herhalende GERD
Die gebruiklike dosis vir langtermyn behandeling is 20 mg **PANTOR** per dag. Indien GERD terugkeer of as die simptome vererger terwyl die daaglikse dosis van 20 mg **PANTOR** per dag geneem word, mag jou dokter die dosis tot 40 mg **PANTOR** per dag verhoog.
Nadat genesing bereik is, sal die dokter weer die dosis tot **20 mg PANTOR** per dag verminder.
Bejaarde pasiënte
Geen dosisaanpassing is by bejaardes nodig nie.
Ingekorte nier- en lewerfunksie
Geen dosisaanpassing is in die teenwoordigheid van ingekorte nierfunksie nodig nie.
'n Daaglikse dosis van 20 mg **PANTOR** behoort nie by pasiënte met lig tot matig ernstige lewerinkorting oorskry te word nie.

Indien jy meer PANTOR gebruik as wat jy behoort te gebruik
In 'n geval van oordosis, moet jy jou dokter of apteker raadpleeg. As albei nie beskikbaar is nie, kontak die naaste hospitaal. Jy moet altyd die tablette en die karton saam met jou na die hospitaal neem sodat die dokter weet wat geneem is.

Indien jy vergeet om PANTOR te neem
Indien jy 'n dosis oorslaan, neem dit so gou as moontlik. Indien dit egter amper tyd is vir jou volgende dosis, moet jy die vergete dosis oorslaan en terugkeer tot jou gereelde doseringskedule. Moenie 'n dubbele dosis neem om op te maak vir vergete dosisse nie.

MOONTLIKE NEWE-EFFEKTE
PANTOR kan newe-effekte veroorsaak.
Nie alle newe-effekte wat vir **PANTOR** aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou vererger of as jy enige nadelige effekte ondervind terwyl hierdie medisyne geneem word, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

Vertel jou dokter dadelik indien:
- jy agterkom dat jou mond of keel seer is, of as velreaksies met blaasvorming of ulserasie, swelling van die mond, lippe, of tong voorkom, of as jy 'n vinniger polsslag of toename in sweet ondervind.
- veluitslag met swelling, blaasvorming of afskilfering van die vel, vel verlies en bloeding rondom die oë, neus, mond of geslagsdele en vinnige agteruitgang van jou algemene gesondheid, of veluitslag as blootstelling aan die son plaasvind.
- jou vel of die wit dele van jou oë geler word as normaal.
- of nierprobleme soos pynlike urinering en pyn in die onderste deel van die rug met koors.

Ander newe-effekte mag insluit:
Frekwent: Hoofpyn, hardlywigheid, wind, maagpyn en diarree.
Minder frekwent: Veluitslag, jeukerigheid, naarheid, braking, duiseligheid of versteurde visie, droë mond, spierpyn en gewrigpyn.

BERGING EN WEGDOENING VAN PANTOR
Bewaar alle medisyne buite bereik van kinders.
Bewaar by of benede 25 ºC in 'n droë plek en beskerm teen lig.
Hou die verpakte tablette in hul stolpverpakkings en karton totdat 'n dosis geneem moet word.
Moenie na die vervaldatum wat op die etiket genoem word, gebruik nie.
Gee alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

AANBIEDING VAN PANTOR
PANTOR 20: 30s (3 x 10) in Alu/Alu stolpverpakkingstroke.
PANTOR 40: 30s (3 x 10) in Alu/Alu stolpverpakkingstroke.

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REGISTRASIENOMMER
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