

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

LANCAP 15 mg (capsules)

LANCAP 30 mg (capsules)

COMPOSITION

LANCAP 15 mg: Each capsule contains 15 mg lansoprazole.

LANCAP 30 mg: Each capsule contains 30 mg lansoprazole.

PHARMACOLOGICAL CLASSIFICATION

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

PHARMACOLOGICAL ACTION

Lansoprazole is an inhibitor of the gastric H⁺ K⁺-ATPase (proton pump).

Lansoprazole inhibits gastric acid secretion in a dose related manner irrespective of the source of stimulation. Gastric secretory functions recover gradually following discontinuation of the medicine. Lansoprazole has no effect on histamine, gastrin or cholinergic receptors.

Pharmacokinetics:

Following oral administration, lansoprazole is well absorbed with a resultant bioavailability of approximately 78%. The bioavailability is decreased if lansoprazole is taken with food. Peak serum concentrations are achieved approximately 1-2 hours following ingestion.

Lansoprazole is highly protein bound (97%).

Lansoprazole is extensively metabolised via the hepatic cytochrome P450 system to the inactive, sulphated metabolites – sulphone, sulphide and 5-hydroxylansoprazole. The half life for lansoprazole is 1,4 to 1,5 hours.

The main route of elimination is via the bile with 15-30% of lansoprazole been excreted via the kidneys as the hydroxylated metabolite.

INDICATIONS

- **LANCAP 30 mg** is indicated for the short-term treatment of gastric and duodenal ulcers and reflux oesophagitis.
- **LANCAP 15 mg** is indicated for the short-term management of mild functional dyspepsia and for the prevention of relapse of gastro-oesophageal reflux.
- **LANCAP** is indicated for *Helicobacter pylori*-positive duodenal ulcers in conjunction with appropriate antibiotics as part of an eradication programme.

CONTRA-INDICATIONS

- Hypersensitivity to lansoprazole or to any of the ingredients.
- Pregnancy and lactation.
- Liver impairment.

WARNINGS

Safety and efficacy in children has not been established.

Treatment with **LANCAP** may alleviate the symptoms of malignant ulcers and can delay diagnosis. Therefore, the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded prior to treatment with **LANCAP**.

This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

INTERACTIONS

- Since **LANCAP** is a weak inducer of the cytochrome P450 system, the possibility exists for interactions with drugs which are metabolised via this system.
- Monitoring of patients receiving concomitant warfarin is recommended, since a minor reduction in the concentration of warfarin may occur.

PREGNANCY AND LACTATION

Adequate and well-controlled studies in humans have not been done.

It is not known whether lansoprazole is distributed into breast milk. However, lansoprazole or its metabolites are distributed into the milk of rats. Because lansoprazole has been shown to cause tumorigenic effects in animals, a decision should be made as to whether nursing should be discontinued or the medication withdrawn, taking into account the importance of lansoprazole to the mother.

DOSAGE AND DIRECTIONS FOR USE

LANCAP should preferably be taken before a meal.

Gastric ulcer:

30 mg once a day for up to eight weeks.

Duodenal ulcer:

30 mg once a day for up to four weeks.

LANCAP is indicated for *Helicobacter pylori* positive ulcers, as part of an eradication program with appropriate antibiotics.

Oesophagitis due to gastro-oesophageal reflux:

30 mg once a day for four weeks. Depending on the endoscopic results, a repeat course of 4 weeks may be necessary.

Maintenance treatment for the prevention of gastro-oesophageal reflux:

15 mg once a day for a maximum period of one year.

Functional dyspepsia:

Adults: 15-30 mg once a day for 2 to 4 weeks.

Elderly: No dose adjustment is necessary. However, 30 mg per day is the maximum daily dose.

Renal impairment: No dose adjustment is necessary in renal failure – this also applies to patients on dialysis.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Side-effects:

Haematological:

Less frequent: Thrombocytopenia, anaemia, leucopenia, neutropenia, eosinophilia.

Cardiovascular:

Less frequent: Oedema.

Central nervous system:

Frequent: Headache, dizziness.

Less frequent: Somnolence, insomnia, tremor.

Gastrointestinal:

Frequent: Diarrhoea.

Less frequent: Nausea, abdominal pain, vomiting, constipation, dry mouth, glossitis, taste abnormalities, ulcerative colitis.

Endocrine disorders:

Less frequent: Gynaecomastia, galactorrhoea.

Liver:

Less frequent: Elevation in hepatic enzymes.

Musculoskeletal:

Less frequent: Asthenia, arthralgia, myalgia.

Ocular:

Less frequent: Blurred vision.

Skin:

Frequent: Skin rash or itching.

Less frequent: Alopecia, pruritus, urticaria.

Other:

Less frequent: Fever.

Special precautions:

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Effects related to acid inhibition:

During long-term treatment, gastric glandular cysts have been reported in increased frequency. These physiological changes result from pronounced inhibition of gastric acid secretion.

Decreased gastric acidity increases gastric counts of bacteria normally present in the gastro-intestinal tract. Treatment with **LANCAP** may lead to an increased risk of gastro-intestinal infections such as Salmonella and Campylobacter.

In the presence of symptoms such as, significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, or melaena, and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with **LANCAP** may alleviate symptoms and delay diagnosis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

(See SIDE-EFFECTS AND SPECIAL PRECAUTIONS)

Treatment is symptomatic and supportive.

IDENTIFICATION

LANCAP 15 mg: Capsules filled with white to light brown or slightly pink coloured pellets.

The body of the hard gelatine capsule is white and the cap is red-brownish coloured.

LANCAP 30 mg: Capsules filled with white to light brown or slightly pink coloured pellets.

The body and cap of the hard gelatine capsule are white.

PRESENTATION

LANCAP 15 mg capsules are available in white HDPE bottles closed with a polypropylene tamper-evident/child-resistant cap with mounted desiccant insert containing 30 capsules.

LANCAP 30 mg capsules are available in white HDPE bottles closed with a polypropylene tamper-evident/child-resistant cap with mounted desiccant insert containing 30 capsules.

STORAGE INSTRUCTIONS

Store in a dry place below 25°C.

Keep the capsules in the original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

LANCAP 15 mg: 40/11.4.3/0247

LANCAP 30 mg: 40/11.4.3/0248

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharma Dynamics (Pty) Ltd.

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DATE OF PUBLICATION OF THE PACKAGE INSERT:

27 September 2005

SKEDULERINGSSTATUS

S4

EIENDOMSNAAM EN DOSEERVORM

LANCAP 15 mg (kapsules)

LANCAP 30 mg (kapsules)

SAMESTELLING

LANCAP 15 mg: Elke kapsule bevat 15 mg lansoprasool.

LANCAP 30 mg: Elke kapsule bevat 30 mg lansoprasool.

FARMAKOLOGIESE KLASSIFIKASIE

A.11.4.3 Medisyne wat op die gastro-intestinale weg werk.

FARMAKOLOGIESE WERKING

Lansoprasool is 'n remmer van H⁺ K⁺-ATPase (protonpomp) in die maag.

Lansoprasool rem afskeiding van maagsuur op 'n manier wat met die dosis verband hou onafgesien van die bron van stimulasie. Die afskeiding van maagsuur herstel geleidelik na staking van die medisyne. Lansoprasool het geen effek op histamien-, gastrien- of cholinergiese reseptore nie.

Farmakokinetika:

Na orale toediening word lansoprasool goed geabsorbeer met 'n gevolglike biobeskikbaarheid van ongeveer 78%. Die biobeskikbaarheid is laer as lansoprasool saam met voedsel geneem word. Piekkonsentrasies in die serum word ongeveer 1-2 uur na inname bereik.

Lansoprasool bind tot 'n groot mate (97%) aan proteïene.

Lansoprasool word tot 'n groot mate deur die hepatiese sitochroom P450-stelsel tot onaktiewe gesulfoneerde metaboliete - sulfoon, sulfied en 5-hidroksilansoprasool - gemetaboliseer. Die halfleefyd van lansoprasool is 1,4 tot 1,5 uur.

Die belangrikste roete van uitskeiding is deur die gal terwyl 15-30% lansoprasool as die gehidroksileerde metaboliet deur die niere uitgeskei word.

INDIKASIES

- **LANCAP 30 mg** is aangedui vir die korttermynbehandeling van gastriese en duodenale ulkuse en refluksesofagitis.
- **LANCAP 15 mg** is aangedui vir die korttermynbeheer van ligte funksionele dispepsie en vir die voorkoming van terugkeer van gastro-esofageale refluks.
- **LANCAP** is saam met geskikte antibiotika aangedui vir *Helicobacter pylori*-positiewe duodenale ulkuse as deel van 'n program vir die uitwissing daarvan.

KONTRA-INDIKASIES

- Hipersensitiwiteit teenoor lansoprasool of enige van die bestanddele
- Swangerskap en borsvoeding
- Swak lewerfunksie

WAARSKUWINGS

Die veiligheid en effektiwiteit vir kinders is nie bepaal nie.

Behandeling met **LANCAP** kan die simptome van kwaadaardige ulkuse verlig en die diagnose vertraag. Daarom moet die moontlikheid van 'n kwaadaardige maagseer of 'n kwaadaardige siekte van die oesofagus uitgeskakel word voordat behandeling met **LANCAP** begin.

Hierdie medisyne kan tot lomerigheid en swak konsentrasie lei wat deur die gelyktydige inname van alkohol of ander onderdrukkers van die sentrale senustelsel versterk kan word. Pasiënte moet gewaarsku word om, veral aan die begin van behandeling, nie motor te bestuur of masjinerie te hanteer of moontlike gevaarlike take uit te voer waar 'n gebrek aan konsentrasie tot ongelukke kan lei nie.

INTERAKSIES

- Omdat **LANCAP** 'n swak induseerder van die sitochroom P450-stelsel is, bestaan die moontlikheid vir interaksies met middels wat deur hierdie stelsel gemetaboliseer word.
- Monitoring van pasiënte wat terselfdertyd warfarien ontvang, word aanbeveel, omdat 'n klein afname in die konsentrasie van warfarien kan voorkom.

SWANGERSKAP EN BORSVOEDING

Geen voldoende en goed gekontroleerde studies met mense is gedoen nie.

Dit is nie bekend of lansoprasool in borsmelk uitgeskei word nie. Lansoprasool of sy metaboliete word egter in die melk van rotte uitgeskei. Omdat dit aangetoon is dat lansoprasool tumorigeniese effekte in diere het, moet besluit word of borsvoeding gestaak en of die medikasie onttrek moet word terwyl die belangrikheid van lansoprasool vir die moeder in ag geneem moet word.

DOSIS EN GEBRUIKSAANWYSINGS

LANCAP moet verkieslik voor etes gedrink word.

Maagseer:

30 mg een keer per dag vir tot agt weke.

Duodenale ulkus:

30 mg een keer per dag vir tot vier weke.

LANCAP is saam met geskikte antibiotika aangedui vir *Helicobacter pylori*-positiewe ulkuse as deel van 'n uitwissingsprogram.

Esofagitis vanweë gastro-esofageale refluks:

30 mg een keer per dag vir vier weke.

Afhangende van die uitslag van die endoskopie kan 'n opvolgkursus van 4 weke nodig wees.

Onderhoudsbehandeling vir die voorkoming van gastro-esofageale refluks:

15 mg een keer per dag vir 'n maksimum periode van een jaar.

Funksionele dispepsie:

Volwassenes: 15-30 mg een keer per dag vir 2 tot 4 weke.

Bejaardes: Geen aanpassing in die dosis is nodig nie. 30 mg per dag is egter die maksimum daaglikse dosis.

Swak nierfunksie: Geen aanpassing in die dosis is tydens nierversaking nodig nie - dit geld ook vir pasiënte wat dialise ondergaan.

NEWE EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Neuwe-effekte:

Bloedversteurings:

Minder dikwels: trombositopenie, anemie, leukopenie, neutropenie, eosinofilie

Vaskulêre versteurings:

Minder dikwels: edeem

Versteurings van senustelsel:

Dikwels: hoofpyn, duiseligheid

Minder dikwels: lomerigheid, slaaploosheid, tremor

Gastro-intestinale versteurings:

Dikwels: diarree

Minder dikwels: naarheid, buikpyn, braking, hardlywigheid, droë mond, glossitis, smaakabnormaliteite, ulseratiewe kolitis

Versteurings van endokrienstelsel:

Minder dikwels: ginekomastie, galaktorree

Hepatobiliêre versteurings:

Minder dikwels: toename in lewerensiem

Muskuloskeletale versteurings:

Minder dikwels: astenie, artralgie, mialgie

Versteurings van die oë:

Minder dikwels: dowwe visie

Velversteurings:

Dikwels: veluitslag of jeuk

Minder dikwels: alopesie, pruritus, urtikarie

Algemene versteurings:

Minder dikwels: koors.

Spesiale voorsorgmaatreëls:

Die diagnose van refluksesofagitis moet met 'n endoskopie bevestig word.

Effekte op die remming van suurafskeiding:

Tydens langtermynbehandeling is 'n hoër voorkoms van gastriese glandulêre siste gerapporteer. Hierdie fisiologiese veranderinge ontstaan vanweë uitgesproke remming van die afskeiding van maagsuur.

Laer suurgehalte in die maag verhoog die tellings van bakterieë wat normaalweg in die gastro-intestinale weg teenwoordig is. Behandeling met **LANCAP** kan 'n hoër risiko inhou vir gastro-intestinale infeksies soos deur Salmonella en Campylobacter lei.

As daar simptome is soos beduidende onbeplande gewigsverlies, aanhoudende braking, disfagie, hematemese of malena en as daar 'n maagseer is of een vermoed word, moet kwaadaardigheid uitgeskakel word, omdat behandeling met **LANCAP** die simptome kan verlig en die diagnose kan vertraag.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

(kyk NEWE-EFFEKTE en SPESIALE VOORSORGMAATREËLS).

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

LANCAP 15 mg: Kapsules gevul met wit tot ligbruin of effens pienk gekleurde korrels. Die romp van die harde gelatienkapsule is wit en die doppie is rooibruin.

LANCAP 30 mg: Kapsules gevul met wit tot ligbruin of effens pienk gekleurde korrels. Die romp en die doppie van die harde gelatienkapsule is wit.

AANBIEDING

LANCAP 15 mg kapsules is beskikbaar in wit HDPE-bottels verseël met 'n peutervrye/kindbestande polipropileenprop met 'n gemonteerde droogmiddel wat 30 kapsules bevat.

LANCAP 30 mg kapsules is beskikbaar in wit HDPE-bottels verseël met 'n peutervrye/kindbestande polipropileenprop met 'n gemonteerde droogmiddel wat 30 kapsules bevat.

BERGINGSINSTRUKSIES

Bewaar in 'n droë plek benede 25 °C.

Hou die kapsules in die oorspronklike houer totdat dit benodig word.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS

LANCAP 15 mg: 40/11.4.3/0247

LANCAP 30 mg: 40/11.4.3/0248

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

27 September 2005