

PATIENT INFORMATION LEAFLET: Lancap 15 mg and 30 mg

Please read this leaflet carefully before taking LANCAP capsules.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine 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.

Scheduling Status:

Schedule 2: Short-term symptomatic relief of heartburn and hyperacidity

Schedule 4: All other indications

Proprietary name, Strength and Pharmaceutical Form:

LANCAP 15 MG capsules (each capsule contains 15 mg lansoprazole)

LANCAP 30 MG capsules (each capsule contains 30 mg lansoprazole)

1. WHAT LANCAP CONTAINS

Active ingredient:

Lansoprazole

Inactive ingredients:

Sugar spheres, Povidone K-30, Disodium hydrogen phosphate dehydrate, Sucrose, Maize starch, Sodium lauryl sulphate, Methacrylic acid – ethyl acrylate copolymer (1:1) 30% dispersion, Talc, Polyethylene Glycol 6000, Titanium dioxide, Polysorbate 80, and Gelatine capsules.



2. WHAT LANCAP IS USED FOR

Schedule 2

- **LANCAP 15 MG** is used for short-term symptomatic relief of heartburn and hyperacidity at a maximum daily dose of 15 mg for a maximum period of 14 days.

Schedule 4

- **LANCAP 30 MG** is used in the short-term treatment of gastric (stomach) and duodenal (small intestine) ulcers and inflammation of oesophagus due to reflux of stomach acid.
- **LANCAP 15 MG** is used in the short-term management of mild functional dyspepsia (indigestion) and to prevent reflux of the stomach acid into the oesophagus.
- **LANCAP** is indicated for *Helicobacter pylori*- positive duodenal (small intestine) ulcers in conjunction with appropriate antibiotics as part of an eradication programme.

3. BEFORE YOU TAKE LANCAP

Do not take LANCAP:

- If you are hypersensitive (allergic) to lansoprazole or any of the other ingredients of LANCAP.
- If you are pregnancy or breast feeding your infant.
- If you have liver impairment.

Take special care with LANCAP:

It is not yet known whether **LANCAP** is safe and effective in children.

LANCAP may make you drowsy and impair your concentration (see "Driving and using machinery").



LANCAP may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD) (you may develop diarrhoea that does not improve). Contact your doctor or healthcare professional as soon as possible

Taking LANCAP with food or drink:

If you take the capsules within 30 minutes of food intake, it may result in lower lansoprazole plasma levels. Therefore, you should take **LANCAP** before meals, preferably in the morning.

Pregnancy and breast-feeding:

You should not take **LANCAP** while you are pregnant or breast feeding your baby. Please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

This medicine may impair your concentration and lead to drowsiness. If you simultaneously use alcohol or other central nervous system depressants, the drowsiness may be aggravated. Do not take charge of vehicles or machinery or perform potentially hazardous tasks where loss of concentration could lead to accidents.

Using other medicines with LANCAP:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **LANCAP** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you are using warfarin, since **LANCAP** may reduce the concentration of warfarin.

4. HOW TO USE LANCAP

Always take **LANCAP** exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

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

Take **LANCAP** before a meal, preferably in the morning.

Schedule 2

Heartburn and hyperacidity:

One **LANCAP 15 MG** capsule daily for up to a maximum of 14 days.

Please consult your doctor when symptoms persist, worsen or continue during and after treatment.

Schedule 4

Stomach ulcer:

The usual adult dose is 30mg once a day for up to eight weeks.

Small intestine ulcer:



30 mg once a day for up to four weeks. Your doctor may combine **LANCAP** with antibiotic treatment.

Inflammation of the oesophagus:

30 mg once a day for four weeks. Your doctor may continue the treatment for another 4 weeks.

In order to prevent the gastro-oesophageal reflux, your doctor may prescribe 15 mg once a day for a maximum period of one year.

Indigestion:

The usual adult dose is 15 to 30 mg once a day for 2 to 4 weeks.

Elderly patients: You should not use more than 30mg lansoprazole per day.

If you take more LANCAP than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take LANCAP:

If you missed a dose, take it as soon as you remember. However, if it is almost time for your next dose, continue to take the next capsule at the usual time. Do not take a double dose to make up for the forgotten individual doses.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.



5. POSSIBLE SIDE EFFECTS

LANCAP can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

LANCAP may cause dizziness and headache.

Contact your doctor if you experience any of the following:

- Diarrhoea, skin rash or itching
- Stomach pain, joint or muscle pain
- Changes in your appetite, nausea, vomiting or constipation
- Flu-like symptoms and increased cough

6. STORAGE AND DISPOSAL OF LANCAP

- Store in a dry place at or below 25°C.
- Keep the capsules in the original container until required for use.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the capsules after the expiry date printed on the container.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

7. PRESENTATION OF LANCAP

LANCAP 15 MG capsules are available in white plastic bottles closed with a plastic tamper-evident cap containing 7, 14, 28 or 30 capsules.



LANCAP 30 MG capsules are available in white plastic bottles closed with a plastic tamper-evident cap containing 14, 28 or 30 capsules.

8. IDENTIFICATION OF LANCAP

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 capsules are white.

9. REGISTRATION NUMBER

LANCAP 15 MG: 40/11.4.3/0247

LANCAP 30 MG: 40/11.4.3/0248

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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