

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:****S4****PROPRIETARY NAME AND DOSAGE FORM:****LANCAP 15 mg capsules****LANCAP 30 mg capsules****Read all of this leaflet carefully before you start taking LANCAP.**

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

1. WHAT LANCAP CONTAINS:

The active substance is lansoprazole.

The other ingredients are disodium hydrogen phosphate dehydrate, gelatine capsules, maize starch, methacrylic acid – ethyl acrylate copolymer (1:1) 30 % dispersion, polyethylene glycol 6000, polysorbate 80, povidone K-30, sodium lauryl sulphate, sucrose, sugar spheres, talc and titanium dioxide.

LANCAP contains sugar (sucrose) in the following quantities:

LANCAP 15 mg (15,55 mg), **LANCAP 30 mg** (33,10 mg) (see **Important information about some of the ingredients of LANCAP**).

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2. WHAT LANCAP IS USED FOR:

- **LANCAP** 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** 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** (see **WHAT LANCAP CONTAINS**)
- if you are pregnant or breastfeeding your infant
- if you have severe liver impairment
- if you are on HIV medicines such as atazanavir or nelfinavir.

Take special care with LANCAP:

- if you experience symptoms such as unintentional weight loss, recurrent vomiting, difficulty in swallowing, blood in vomit, dark sticky faeces or if you suspect a stomach ulcer tell your doctor because **LANCAP** can mask the symptoms of cancerous ulcers
- **LANCAP** may affect the kidneys (interstitial nephritis). Inform your doctor if you experience any pain while urinating or lower back pain
- if you are using **LANCAP** over a long period of time (e.g. longer than 3 years) this may lead to a vitamin B12 deficiency
- **LANCAP** may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD) (you may develop diarrhoea that does not stop). Contact your doctor or healthcare provider as soon as possible

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- **LANCAP** may make you drowsy and impair your concentration (see “Driving and using machinery”)
- **LANCAP** may increase your risk for osteoporosis-related bone fractures of the hip, wrist or spine. Inform your doctor if you have osteoporosis.
- if you have been told you have low magnesium levels in your blood, or if you experience fatigue, tetany (painful contractions of jaw and neck muscles), delirium, convulsions, dizziness and a change from normal heartbeat, or if you are taking medicines such as digoxin or diuretics (water tablets), tell your doctor as **LANCAP** can further reduce your magnesium levels
- if you are taking methotrexate
- if you are taking **LANCAP** for a long period of time, you may be at risk of gastrointestinal infections such as *Salmonella*, and *Campylobacter*
- if you have porphyria, inform your doctor before taking **LANCAP**
- Your doctor may conduct a test known as an endoscopy before prescribing **LANCAP**.

Taking LANCAP with food and drink:

If you take **LANCAP** 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 breastfeeding:

You should not take **LANCAP** while you are pregnant or breastfeeding your baby (see **Do not take LANCAP**).

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **LANCAP**.

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LANCAP 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.

Important information about some of the ingredients of LANCAP:

LANCAP contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **LANCAP**.

Taking other medicines with LANCAP:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

The following medicines may interact with **LANCAP**:

LANCAP may weaken the effects of some medicines such as:

- Warfarin (to prevent blood clots)
- Antipyrine, indomethacin, ibuprofen, or other nonsteroidal anti-inflammatory drugs (NSAIDS); (medicines used to treat pain)
- Oral contraceptives,
- Phenytoin (to treat epilepsy),
- Propranolol (to treat high blood pressure),
- Prednisone (to treat allergic reactions),
- Diazepam (to relax muscles or to treat anxiety)
- Clarithromycin (a type of antibiotic)
- Theophylline (to treat a tight chest).

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LANCAP may intensify the effects of some medicines such as:

- Tacrolimus (to prevent transplant rejection)
- Digoxin (to treat heart problems)
- Methotrexate (to treat cancer).

The effect of **LANCAP** may be weakened by:

- Sucralfate (to treat ulcers)
- Rifampicin (to treat TB)
- St John's Wort (to treat depression).

LANCAP can affect the absorption of these medicines:

- Itraconazole, ketoconazole, posaconazole, voriconazole (to treat fungal infections)
- Ampicillin (antibiotic)
- Iron supplements
- Atazanavir, nelfinavir (to treat HIV)
- Dasatinib, erlotinib (to treat cancer).

If you are taking fluvoxamine (used to treat depression), the effect of **LANCAP** can be intensive.

LANCAP may affect certain diagnostic tests for certain hormonal and nervous system tumours as well as the urea breath test for bacterial infections (*Helicobacter pylori*).

4. HOW TO TAKE LANCAP

Do not share medicines prescribed for you with any other person.

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

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

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The usual dose is one **LANCAP 15 mg** or one **LANCAP 30 mg** capsule daily depending on the condition you are being treated for.

Your doctor will tell you how long treatment with **LANCAP** will last. Do not stop treatment early because your condition may not be adequately treated and may worsen.

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

If you take more LANCAP than you should:

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

If you forget to take a dose of 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 **LANCAP**, ask your pharmacist for some hints.

5. POSSIBLE SIDE EFFECTS

LANCAP can have side effects.

Not all side effects reported for **LANCAP** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **LANCAP**, please consult your healthcare provider for advice.

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

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

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

- yellowing of the skin and eyes, also called jaundice
- **LANCAP** may reduce the number of white cells in your blood, which may decrease your ability to fight infections. If you experience any infection with symptoms such as fever or a serious deterioration in your general health, or a fever with symptoms such as sore throat/mouth, or bladder problems, you should see your doctor immediately.
- chest pain, angina, changes in the way your heart beats, for example, if you notice it beating faster, slower, harder or irregular, difficulty in breathing,
- a persistent, scaly red patch on the skin with irregular borders that sometimes crusts or bleeds (skin cancer)
- very serious skin reactions with reddening, blistering, severe inflammation and skin loss
- serious kidney problems: less urine than is normal for you, swelling of the legs, ankles or feet, nausea or extreme tiredness, seizures or coma in severe cases.

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

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Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness, diarrhoea, dry mouth or throat, nausea, vomiting (sometimes with blood), constipation, gas pass through anus, stomach pain, bloated, changes in test results (e.g. raised liver enzymes), itching, scaly red or purple inflamed skin or rash, fatigue.

Less frequent side effects:

- changes in your blood cell count, or amount of sugar in your blood which may leave you feeling weak, tired, looking pale or generally feeling unwell.
- swelling of the neck due to enlargement of the thyroid gland.
- dehydration, pain, stiffness or swelling in joints, extreme thirst, swelling of the hands or feet, neck or pelvic pain, neck or muscle stiffness, weight gain or loss, problems with smell or taste, muscle weakness or cramps.
- abnormal dreams, mood changes such as agitation, hostility, memory loss, anxiety, laziness, confusion, a feeling of detachment from oneself, depression, mood swings, hallucinations (seeing or hearing things which are not there), increased or decreased sex drive, nervousness, distress, unable to sleep.
- fit, double vision, paralysis on one side of the body, excessive abnormal body movements, stiff muscles, reduced sensitivity to touch, tingling or burning of the skin, restlessness, strange thoughts, sleepiness, tremor, vertigo (a sensation of spinning when standing still).
- abnormal or blurred vision, itchy, water or red eyes, dry eyes, eye pain, sensitivity of eyes to the light, blurred vision and other problems with your vision including double vision.
- deafness, ear problems, ear ache, ringing of the ears.
- flushing, dizziness and feeling lightheaded, migraine, fainting.

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- difficulty in breathing/ tight chest, increased coughing, shortness of breath, nose bleed or coughing blood, hiccups, sore or scratchy throat or pain swallowing, sharp chest pain that gets worse when you breathe, runny or blocked nose, sinus headache, abnormal noise when breathing.
- bleeding gums, increased appetite or saliva, mouth ulcer, blood in stool, abnormal tastes, thirst, tongue disorder, pain inside the mouth due to white spots on your tongue, inner cheeks, gums, palate and/or tonsils, feeling that you need to have a bowel movement, even if you already have had one, inflammation of the mouth and lips, pancreatitis (upper abdominal pain that radiates into the back, which may be aggravated by eating foods high in fat).
- acne, hair loss, dry skin, problems with nails, sweating, sensitivity of skin to light, peeling of skin over large areas of the body.
- painful, swollen or stiff joints, bone or joint problems, leg cramps, muscle or bone pain, muscle weakness, fracture of the wrist, hip or spine, neck pain or stiffness, pelvic pain.
- pain or discomfort on urination, blood in the urine, back pain (kidney pain), excessive or abnormally large production of urine, frequent urination or the need to constantly urinate.
- abnormal periods (heavy, lighter, longer or more painful), breast enlargement or tenderness in both men and women, impotence, whitish or yellowish discharge, penis disorder or inflamed vagina.
- feeling of weakness, chest pain, chills, fever, flu symptoms, smelly breath, infection, generally feeling unwell, swelling or water retention.
- increased sodium, cholesterol and triglyceride (fat) levels).

Side effects of unknown frequency:

- increased magnesium in your blood.

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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORAGE AND DISPOSING OF LANCAP

- Store in a dry place at or below 25 °C.
- Keep the capsules in the original container until required for use.
- STORE 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)