

PACKAGE LEAFLET

Package leaflet: Information for the patient

Lanthanum 500 mg chewable tablets

Lanthanum 750 mg chewable tablets

Lanthanum 1000 mg chewable tablets

lanthanum

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lanthanum is and what it is used for
2. What you need to know before you take Lanthanum
3. How to take Lanthanum
4. Possible side effects
5. How to store Lanthanum
6. Contents of the pack and other information

1. What Lanthanum is and what it is used for

Lanthanum is used to lower the phosphate level in the blood of adult patients with chronic kidney disease.

Patients who have kidneys that do not work properly are not able to control the level of phosphate in the blood. The amount of phosphate in the blood then rises (your doctor may call this hyperphosphataemia).

Lanthanum is a medicine which reduces the body's absorption of phosphate from food by binding with it in your digestive tract. Phosphate which have bonded to Lanthanum cannot be absorbed through the intestinal wall.

2. What you need to know before you take Lanthanum

Do not take Lanthanum:

- if you are allergic to Lanthanum or any of the other ingredients of this medicine (listed in section 6).
- if you have too little phosphate in your blood (hypophosphataemia).

Warnings and precautions

Talk to your doctor or pharmacist before taking Lanthanum if you know that you have, or have had, any of the following conditions:

- stomach or intestinal cancer,
- inflammatory bowel disease including ulcerative colitis or Crohn's disease,
- abdominal surgery, or infection or inflammation of the abdomen/bowel (peritonitis),
- stomach or intestinal ulcers,
- blockage of the intestine or slow motility (movement) in the intestine (e.g. constipation and stomach complications due to diabetes),
- reduced liver or kidney function.

Reduced kidney function

If you have reduced kidney function your doctor may decide to check the level of calcium in your blood from time to time. If you have too little calcium, you may then be given extra calcium.

Reduced liver function

If you have impaired liver function your doctor should monitor your liver function tests carefully.

If you need to have an x-ray, please inform your doctor that you are taking Lanthanum as it may affect the results.

If you need to have a gastrointestinal endoscopy, please inform your doctor that you are taking Lanthanum because the endoscopist might detect lanthanum deposits in the digestive tract.

It is very important to chew completely Lanthanum tablets and not to swallow them whole or incompletely chewed. This will reduce the risk of adverse gastrointestinal complications like rupture in the intestine wall, blockage in the intestine, constipation (see section 4).

Other medicines and Lanthanum

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

This medicine can affect how certain medicines are absorbed from your digestive tract. If you are taking chloroquine (for rheumatism and malaria), ketoconazole (for fungal infections), tetracycline or doxycycline antibiotics they should not be taken within 2 hours before or after taking Lanthanum.

It is not recommended that you take oral floxacin antibiotics (including ciprofloxacin) within 2 hours before or 4 hours after taking this medicine.

If you are taking levothyroxine (for an under active thyroid) it should not be taken within 2 hours before or after taking Lanthanum. Your doctor may want to monitor the levels of thyroid-stimulating hormone (TSH) in your blood more closely.

Lanthanum with food and drink

This medicine should be taken with, or immediately after food. See Section 3 for instructions on how to take Lanthanum.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Lanthanum should not be taken during pregnancy.

Breast-feeding

As it is not known whether the drug can be transferred to a child in breast-milk, you should not breast-feed whilst taking Lanthanum. If you are breast-feeding, ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Dizziness and vertigo (a feeling of dizziness or “spinning”) are uncommon side effects reported by patients taking Lanthanum. If you experience these side effects, it may affect your ability to drive or operate machinery.

3. How to take Lanthanum

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should take Lanthanum with food or immediately after food.
Side effects such as nausea and vomiting are more likely if you take this medicine before your meal.

The tablets must be chewed completely and not swallowed whole. To aid with chewing the tablets may be crushed. Additional fluid is not necessary. If you find chewing the tablets difficult, talk to your doctor as other dosage forms are available in the market.

Your doctor will tell you how many tablets you must take with each meal (your daily dose will be divided between meals). The number of tablets that you take will depend on:

- your diet (the amount of phosphate in the food you eat),
- your blood phosphate level.

Every 2-3 weeks your doctor will check the level of phosphate in your blood and may increase your dose until the level of phosphate in your blood is acceptable.

Lanthanum works by binding phosphate from the food in your gut. It is very important to take Lanthanum at every meal. If you change your diet, contact your doctor as you may need to take extra Lanthanum. Your doctor will tell you what to do in this case.

If you take more Lanthanum than you should

If you take too many tablets, contact your doctor to assess the risk and obtain advice. Symptoms of overdose may be nausea and headaches.

If you forget to take Lanthanum

It is important to take this medicine with every meal.

If you forget to take your Lanthanum tablets, then take the next dose with your next meal.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious. If you get any of the following side effects, seek immediate medical attention:

- Rupture in the intestinal wall.
Signs include severe stomach pain, chills, fever, nausea, vomiting, or a tender abdomen (rare side effect - may affect up to 1 in 1,000 people).
- Blockage in the intestine.
Signs include severe bloating; abdominal pain, swelling or cramps; severe constipation (uncommon side effect - may affect up to 1 in 100 people).
- Contact your doctor if you experience new or severe constipation, it could be an early sign of a blockage in your intestine. Constipation is a common side effect (may affect 1 in 10 people).

Other side effects include the following:

Very Common (may affect more than 1 in 10 people):

- feeling sick (nausea),
- being sick (vomiting),
- diarrhoea,

- stomach pain,
- headache,
- itching,
- hives (urticaria)
- rash (a noticeable change in the texture or colour of your skin).

Common (may affect up to 1 in 10 people):

- heartburn,
- wind (flatulence),
- hypocalcaemia (too little calcium in your blood). The symptoms of which can include tingling in the hands and feet, muscle and abdominal cramps or spasms of the facial and feet muscles.

Uncommon (may affect up to 1 in 100 people):

- tiredness,
- feeling of discomfort,
- chest pain,
- weakness,
- swollen hands and feet,
- body pain,
- dizziness
- vertigo (sensation that you, or the environment around you, is moving or spinning.),
- belching (expelling air from the stomach through the mouth),
- gastroenteritis (inflammation of the stomach and intestines),
- Indigestion,
- irritable bowel syndrome (common, long-term condition of the digestive system. It can cause bouts of stomach cramps, bloating, diarrhoea and/or constipation),
- dry mouth,
- tooth disorders,
- inflammation of the gullet or mouth,
- loose stools,
- increases in certain liver enzymes, parathyroid hormone;
- aluminium, calcium and glucose in the blood,
- increased or reduced phosphate level in the blood,
- thirst,
- weight decrease,
- joint pain,
- muscle pain,
- osteoporosis (weakness and thinning of the bones),
- lack of and increased appetite,
- inflammation of the larynx,
- loss of hair,
- increased sweating,
- taste disturbance,
- increased white blood cell count.

Unknown (frequency cannot be estimated from the available data):

- product residue present in digestive tract

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lanthanum

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, and bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lanthanum contains

- The active substance is lanthanum (as Lanthanum hydrate). Each chewable tablet contains 500 mg, 750 mg or 1000 mg of lanthanum (as Lanthanum hydrate).
- The other ingredients are hypromellose, cellulose microcrystalline & guar gum, cellulose microcrystalline, hydroxypropylcellulose, silica colloidal anhydrous, acesulfame potassium and magnesium stearate.

What Lanthanum looks like and contents of the pack

500 mg chewable tablets

The chewable tablets of Lanthanum 500 mg are white to off-white, round, flat-faced, bevelled-edge, debossed with 'M on one side of the tablet and 'LC' over '500' on the other side.

Pack sizes: This medicine is available in bottle packs containing 1 bottle with 45 tablets or 2 bottles with 45 tablets each (90 tablets).

750 mg chewable tablets

The chewable tablets of Lanthanum 750 mg are white to off-white, round, flat-faced, bevelled-edge, debossed with 'M on one side of the tablet and 'LC' over '750' on the other side.

Pack sizes: This medicine is available in bottle packs containing 1 bottle with 15 tablets or 6 bottles with 15 tablets each (90 tablets).

1000 mg chewable tablets

The chewable tablets of Lanthanum 1000 mg are white to off-white, round, flat-faced, bevelled-edge, debossed with 'M on one side of the tablet and 'LC' over '1000' on the other side.

Pack sizes: This medicine is available in bottle packs containing 1 bottle with 15 tablets or 6 bottles with 15 tablets each (90 tablets).

Not all pack sizes may be marketed.

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This leaflet was last revised in 04/2023