

Package leaflet: Information for the patient

Lanthanum Orifarm 500 mg chewable tablets
Lanthanum Orifarm 750 mg chewable tablets
Lanthanum Orifarm 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, pharmacist or nurse.
- 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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] 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).

[Invented name] contains the active substance lanthanum which reduces the body's absorption of phosphate from food by binding with it in your digestive tract. Phosphate which has bonded to [Invented name] cannot be absorbed through the intestinal wall.

2. What you need to know before you take [Invented name]

Do not take [Invented name]

- 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).
- if you have blockage of the bowel (bowel obstruction).

Warnings and precautions

Talk to your doctor or pharmacist before taking [Invented name] if you know that you have, or have had, any of the following:

- 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.

It is very important to chew completely [Invented name] 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).

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.

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

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

Other medicines and [Invented name]

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

[Invented name] can affect how certain drugs 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 [Invented name].

It is not recommended that you take oral floxacin antibiotics (including ciprofloxacin) within 2 hours before or 4 hours after taking [Invented name].

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

[Invented name] with food and drink

[Invented name] should be taken with, or immediately after food. See Section 3 for instructions on how to take [Invented name].

Pregnancy and breast-feeding

[Invented name] should not be taken during pregnancy. 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.

As it is not known whether the drug can be transferred to a child in breast-milk, you should not breastfeed whilst taking [Invented name]. 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 [Invented name]. If you experience these side effects, it may affect your ability to drive or operate machinery.

[Invented name] contains glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

3. How to take [Invented name]

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 [Invented name] with, or immediately after food. Side effects such as nausea and vomiting are more likely if you take [Invented name] 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 an oral powder form of this medicine is available.

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.

To start with, the daily dose of [Invented name] will usually be 1 tablet with each meal (3 tablets per day).

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.

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

If you take more [Invented name] 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 [Invented name]

It is important to take [Invented name] with every meal.

If you forget to take your [Invented name] 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, pharmacist or nurse.

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). This is a 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). This is an uncommon side effect (may affect up to 1 in 100 people).
- Contact your doctor if you have new or severe constipation, it could be an early sign of blockage in your intestine. Constipation is a common side effect (may affect 1 in 10 people).

Other less serious side effects include the following:

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

- Nausea, vomiting, diarrhoea, stomach pain, headache, itching, rash.

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

- Heartburn, flatulence.
- Hypocalcaemia (too little calcium in your blood) is also a common side effect; 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 side effects (may affect up to 1 in 100 people):

- Tiredness; feeling of discomfort; chest pain, weakness; swollen hands and feet; body pain; dizziness; vertigo; belching; inflammation of the stomach and intestines (gastroenteritis); indigestion; irritable bowel syndrome; 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; weakness and thinning of the bones (osteoporosis); lack of and increased appetite; inflammation of the larynx; loss of hair; increased sweating; taste disturbance and increased white blood cell count.

Not known (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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

Store below 25 °C. Store in the original package in order to protect from light.

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

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 [Invented name] contains

- The active substance is lanthanum. Each chewable tablet contains 500 mg, 750 mg or 1000 mg lanthanum (as lanthanum carbonate octahydrate).
- The other ingredients are calcium silicate (E 552); silica, colloidal anhydrous; dextrates; glycerol dibehenate; magnesium stearate and talc (E 553b) (see section 2 for further information on dextrates which contains glucose).

What [Invented name] looks like and contents of the pack

500 mg: White coloured, round tablets engraved with '500' on one side and with diameter of 18 mm and thickness of 5 mm.

[Invented name] is available in multipacks comprising 2 bottles, each containing 45 tablets.

750 mg: White coloured, round tablets engraved with '750' on one side and with diameter of 20 mm and thickness of 7 mm.

[Invented name] is available in multipacks comprising 6 bottles, each containing 15 tablets.

1000 mg: White coloured, round tablets engraved with '1000' on one side and with diameter of 22 mm and thickness of 7 mm.

[Invented name] is available in multipacks comprising 6 bottles, each containing 15 tablets.

The plastic bottle is white, opaque containing rayon with a childproof-lock cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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Detailed information on this medicine is available on the web site of {MA/Agency}