

LANFOS

Lanthanum Carbonate Dihydrate

DESCRIPTION

Lanthanum Carbonate belongs to a new class of non-calcium dietary phosphate-binders. In the acid environment of the stomach the La^{3+} ion is released. The ion binds to dietary phosphate to form insoluble Lanthanum phosphate to reduce absorption of dietary phosphate.

COMPOSITION

Lanfos 250 Tablet : Each chewable tablet contains 250 mg of Lanthanum as Lanthanum Carbonate Dihydrate INN.

Lanfos 500 Tablet : Each chewable tablet contains 500 mg of Lanthanum as Lanthanum Carbonate Dihydrate INN.

PHARMACOLOGICAL INFORMATION

Therapeutic class: phosphate binder.

Mechanism of Action: Lanthanum Carbonate is a phosphate binder that reduces absorption of phosphate by forming insoluble Lanthanum phosphate complexes that pass through the GI tract unabsorbed. Both serum phosphate and calcium phosphate product are reduced as a consequence of the reduced dietary phosphate absorption.

PHARMACODYNAMICS

In vitro studies have shown that Lanthanum binds phosphate in the physiologically relevant pH range of 3 to 7. In simulated gastric fluid, Lanthanum binds approximately 97% of the available phosphate at pH 3-5 and 67% at pH 7, when Lanthanum is present in a two-fold molar excess to phosphate. Bile acids have not been shown to affect the phosphate binding affinity of Lanthanum. In order to bind dietary phosphate, Lanthanum Carbonate must be administered with or immediately after meals.

INDICATION

Lanthanum Carbonate is a phosphate binder indicated to reduce serum phosphate in patients with end-stage renal disease (ESRD).

DOSAGE AND ADMINISTRATION

The recommended initial total daily dose of Lanthanum Carbonate is 1,500 mg in divided doses. Titrate every 2 to 3 weeks based on serum phosphate level. Take Lanthanum Carbonate with or immediately after meals.

Lanthanum Carbonate Chewable Tablets: Do not swallow tablets whole. Chew or crush tablet completely before swallowing.

WARNINGS AND PRECAUTIONS

Gastrointestinal Adverse Effects : Serious cases of gastrointestinal obstruction, ileus, subileus, gastrointestinal perforation, and fecal impaction have been reported in patients taking Lanthanum, some requiring surgery or hospitalization. During treatment with Lanthanum Carbonate, physicians and patients should remain vigilant for signs and symptoms of gastrointestinal disorders, especially constipation and abdominal pain/distention, which may indicate bowel obstruction, ileus, or subileus. Treatment with Lanthanum Carbonate should be re-evaluated in patients who develop severe constipation or other severe gastrointestinal signs and symptoms. Advise patients who are prescribed Lanthanum Carbonate Chewable Tablets to chew the tablet completely and not to swallow them whole. Serious gastrointestinal complications have been reported in association with unchewed or incompletely chewed tablets.

DRUG INTERACTIONS

Drugs Binding to Antacids: There is a potential for Lanthanum Carbonate to interact with compounds which bind to cationic antacids (i.e., aluminum-, magnesium-, or calcium-based); therefore, do not administer such compounds within 2 hours of dosing with Lanthanum Carbonate.

Quinolone Antibiotics: Co-administration of Lanthanum Carbonate with quinolone antibiotics may reduce the extent of their absorption. The bioavailability of oral ciprofloxacin was decreased by approximately 50% when taken with Lanthanum Carbonate in a single-dose study in healthy volunteers. Administer oral quinolone antibiotics at least 1 hour before or 4 hours after Lanthanum Carbonate. When oral quinolones are given for short courses, consider eliminating the doses of Lanthanum Carbonate that would normally be scheduled near the time of quinolone intake to improve quinolone absorption.

Levothyroxine: the bioavailability of levothyroxine was decreased by approximately 40% when taken together with Lanthanum Carbonate. Administer thyroid hormone replacement therapy at least 2 hours before or 2 hours after dosing with Lanthanum Carbonate and monitor thyroid stimulating hormone (TSH).

CONTRAINDICATIONS

Contraindicated in bowel obstruction, including ileus and fecal impaction.

ADVERSE DRUG REACTION

The most common adverse reactions for Lanthanum Carbonate were gastrointestinal events, such as nausea, vomiting, and abdominal pain and they generally abated over time with continued dosing. The following adverse reactions have been identified during post-approval use of Lanthanum Carbonate constipation, dyspepsia, allergic skin reactions, and tooth injury while chewing the tablet.

SPECIAL POPULATIONS

Pregnancy : Available data from case reports with use of Lanthanum Carbonate in pregnant women are insufficient to identify a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Use a non-Lanthanum containing phosphate binder in a pregnant woman.

Lactation : There are no data on the presence of Lanthanum Carbonate from Lanthanum Carbonate in human milk, the effects on the breastfed infant, or the effects on milk production. Use a non-Lanthanum containing phosphate binder in a lactating woman.

Pediatric Use : The safety and efficacy of Lanthanum Carbonate in pediatric patients have not been established. The use of Lanthanum Carbonate in this population is not recommended.

Geriatric Use : Of the total number of patients in clinical studies of Lanthanum Carbonate, 32% (538) were ≥ 65 years of age, while 9.3% (159) were ≥ 75 years of age. No overall differences in safety or effectiveness were observed between patients ≥ 65 years of age and younger patients.

OVERDOSE

The symptoms associated with overdose are adverse reactions such as headache, nausea and vomiting. In clinical trials in healthy adults, gastrointestinal (GI) symptoms were reported with daily doses up to 6,000 mg/day of Lanthanum Carbonate administered with food.

STORAGE CONDITION

Store in a cool (below 30° C) and dry place, away from light. Keep out of the reach of children.

PACKAGING

Lanfos 250 Tablet : Each commercial box contains 30 chewable tablets in HDPE bottle.

Lanfos 500 Tablet : Each commercial box contains 30 chewable tablets in HDPE bottle.