

Mosar Enzimático

Mosapride
Pancreatin 6NF
Simethicone

Tablets

Made in Argentina - RX only

FORMULA:

Each tablet contains: Mosapride citrate dihydrate 5.28 mg (equivalent to mosapride citrate 5.0 mg); simethicone 50% 400 mg (equivalent to simethicone 200 mg); pancreatin 6NF 153 mg.

Excipients: sodium croscarmellose, gelatin, povidone, polysorbate 20, microcrystalline cellulose, lactose monohydrate, corn starch, adipic acid, colloidal silicon dioxide, menthol, magnesium stearate, cellulose acetate phthalate, talc, polyethylene glycol 4000, q.s.

INDICATIONS:

Non-ulcerous dyspepsia, accompanying digestive symptoms (heartburn, nausea, vomits, flatulence) in chronic gastritis.

THERAPEUTIC ACTION:

Antidyspeptic, antifatulent. It regulates the digestive motility and accelerates gastric evacuation.

PHARMACOLOGICAL ACTION:

Mosapride citrate is a selective agonist of 5-HT₄ serotonergic receptors present in the intrinsic nerves of the digestive tract, and participates in the increase of acetylcholine release, thus performing a modulating action on digestive motility and an accelerating action on gastric evacuation.

Pancreatin is involved in the digestion of lipids, proteins and carbohydrates, through trypsin, amylase and lipase enzymes.

Simethicone produces the disappearance of the bubbles and small gas chambers of the stomach and the intestine. Simethicone has such effects since it reduces superficial tension.

PHARMACOKINETICS:

Following the oral administration of mosapride citrate, the average peak serum concentration (C_{max} = 30.7 ng/ml) is reached 0.8 hours after taking a 5 mg dose. Mosapride citrate is bound to plasmatic proteins (99.0 %) with a 1 mg/ml concentration. It is mainly metabolized in the liver and it is eliminated through urine and feces.

Pancreatin is a normal component of the body, following the performance of its digestive function is it degraded in situ and partially absorbed in the form of nutrients.

Simethicone is insoluble in water and lipids, thus it is not absorbed in the digestive tract and it is eliminated through feces.

DOSAGE AND ADMINISTRATION:

Administer 2 to 3 tablets daily, three times a day, before meals.

**CONTRAINDICATIONS:**

Hipersensibilidad to the active ingredient or to any of its components. Pregnancy. Nursing mothers. Pediatric patients.

WARNINGS AND PRECAUTIONS:

It should be administered with caution in patients with reduced hepatic and/or renal function. In geriatric patients it might be recommendable to reduce the dose.

PREGNANCY:

The safety of the administration of mosapride citrate during pregnancy has not been proven, thus it shall only be administered if the benefits outweigh the risks.

LACTATION:

Do not administer during this period. Pre-clinical studies have shown that the drug is passed on to maternal milk.

PEDIATRIC USE:

The safety and efficacy of the drug have not been proven in the administration to pediatric patients.

DRUG INTERACTIONS:

The simultaneous administration with anticholinergics (i.e., atropine sulfate, butylscopolamine bromide) may reduce the action of mosapride citrate, thus longer intervals are recommended between the administration of both medications.

ADVERSE REACTIONS:

Digestive tract: diarrhea, soft feces, dry mouth, abdominal pain.

Circulatory tract: palpitations

Laboratory parameters: increase in TGO, TGP, alkaline phosphate and *g*-GTP.

Other rarely frequent adverse events: asthenia, dizziness, vertigo, eosinophilia, increase in neutral fats.

OVERDOSE:

In case of a possible overdose, seek medical attention in the nearest hospital or toxicology center.

HOW SUPPLIED:

Packs containing 30 tablets.

**KEEP OUT OF THE REACH OF CHILDREN.
STORE BELOW 30 °C.**



Compromiso por la Salud

Manufactured by Laboratorios Phoenix S.A.I.C. y F.
Humahuaca 4065/79 (C1192ACC) CABA, Argentina
Av. Gral. J. Lemos 2809 (B1614BHD) Villa de Mayo, Buenos Aires, Argentina
Distributed in Lebanon by Droguerie Phénicia:
Achrafieh-Chahroui Street-Attallah Bldg., Beirut, Lebanon

"The sale packaging of this product has its trade name printed in Braille system, in order to allow its identification by blind patients."



Recyclable
material