Mosar 2.5 mg/5 mg

Mosapride

Coated Tablets

Made in Argentina - Rx Only

FORMULAS:
Each coated tablet of **MOSAR 2.5 mg** contains: Mosapride citrate dihydrate 2.64 mg (equivalent to mosapride citrate 2.5 mg).
Excipients: lactose monohydrate, sodium lauryl sulfate, povidone, microcrystalline celullose, sodium croscarmellose, talc, magnesium stearate, hidroxypropylmethylcelullose, polyethylenglycol 6000, tween 80, sodium saccharine, sodium cyclamate, copolividone, titanium dioxide, q.s.

Each coated tablet of **MOSAR 5 mg** contains: Mosapride citrate dihydrate 5.28 mg (equivalent to mosapride citrate 5.0 mg).
Excipients: lactose monohydrate, sodium lauryl sulfate, povidone, microcrystalline cellulose, sodium croscarmellose, talc, magnesium stearate, hidroxypropylmethylcelullose, polyethylenglycol 6000, sodium saccharine, tween 80, sodium cyclamate, copolividone, titanium dioxide, q.s.

THERAPEUTICAL ACTION
MOSAR regulates digestive motility and accelerates gastric evacuation.

INDICATIONS
Non-ulcerous dyspepsia, digestive symptoms (stomach burning, nausea, vomits) typical of chronic gastritis. Symptoms and lesions associated with gastroesofagic reflux: pyrosis, regurgitations. Maintenance treatment in reflux esofagitis.

PHARMACOLOGICAL ACTION
Mosapride citrate is a selective agonist of 5-HT4 serotonergic receptors present in the intrinsic nerves of the digestive tube, and contributes to increasing the release of acetilcholine, thus it produces a modulating action in digestive motility and an accelerating action in gastric evacuation. Mosapride citrate dihydrate does not block dopaminergic D2 receptors, thus it does not produce extrapyramidal syndromes.

PHARMACOKINETICS
Following the oral administration of mosapride citrate the average peak serum concentration (C_{max}= 30.7 ng/ml) is achieved 0.8 hours after the administration of a 5 mg dose. The mean life is 2 h. Mosapride citrate is bound to plasmatic proteins (99.0 %) with a 1mcg/ml concentration. It is mainly metabolized in the liver and eliminated in urine and feces.

ADMINISTRATION
Adults: Tablets: Administer 15 mg mosapride citrate/day (6 tablets of **MOSAR 2.5 mg** or 3 tablets of **MOSAR 5 mg**), 3 times daily, before or after meals.
In patients with severe hepatic or renal insufficiency, the initial dose should not exceed 7.5 mg/day mosapride, i.e., 2.5 mg, 3 times daily. Geriatric patients do not normally require a different dose. However, it is convenient to administer the drug cautiously in those patients with a certain degree of renal insufficiency or who might suffer side effects; in which case, the dose should be reduced to 7.5 mg/daily, 3 times a day.
Geriatric patients: The dose may be reduced to 7.5 mg mosapride citrate/daily.

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

PRECAUTIONS AND WARNINGS
It shall be administered with caution to patients with hepatic and/or renal insufficiency.
In geriatric patients a reduced administration may be considered. Use cautiously in patients treated with the

19492530/02

following triazolic antimicotic drugs (itraconazole, ketoconazole), macrolids, HIV protease inhibitors and nefazodone.
PREGNANCY: The safety of the administration during pregnancy has not yet been proven, thus this drug shall only be administered if the benefit exceeds the risk.
NURSING MOTHERS: Do not administer during this period. In experimental animals the drug has been reported to pass onto maternal milk.
PEDIATRIC PATIENTS: The safety and efficacy of this product have not been shown in pediatric patients.

INTERACTIONS
The simultaneous administration with anticholinergics (atropine sulfate, butylscopolamine bromide) may reduce the action of mosapride citrate, thus it is recommended to extend administration intervals between both medications. The concomitant use with drugs that are metabolized with cytochrome P450 3A4 (ketoconazole, itraconazole, macrolid antibiotics, HIV protease inhibitors) may increase mosapride plasma concentrations, which may increase the risk of adverse events. The following episodes were observed in laboratory tests in approximately 3.8% of the patients: increase in eosinophils (1.1%) and neutrophils (1%), and in TGO and TGP (0.4% respectively).

ADVERSE EVENTS
Digestive tract: diarrhea, soft feces, dry mouth, abdominal pain.
Circulatory tract: palpitations.
Laboratory parameters: increase in TGO, TGP, alkaline phosphatase, and g-GTP.
Other rarely frequent adverse events: astenia, dizziness, vertigo, eosinophilia, increase in neutral fats.

OVERDOSE
In case of a possible overdose refer to the closest hospital or toxicology center.

PACKAGES
MOSAR 2.5 mg coated tablets: packs containing 20, 30 and 60 coated tablets.
MOSAR 5 mg coated tablets: packs containing 20, 30 and 60 coated tablets.

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

Laboratorios
PHOENIX
Compromiso por la Salud

Manufactured by Laboratorios PHOENIX S.A.I.C. y F.
Humahuaca 4065/79 (C1192ACC) CABA, Argentina
Av. Gral. J. G. Lemos 2809 (B1614BHD) Villa de Mayo, Buenos Aires, Argentina

Distributed in Lebanon by Droguerie Phenicia Achrafieh-Chahrouri Street-Attallah Bldg., Beirut, Lebanon Certificate N° 194340/05.

The sale packaging of this product has its trade name printed in Braille, for the purpose of making its identification easier to blind patients.

Recyclable Material

C. 89447-16
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