Mosar
Mosapride

Coated tablets

Made in Argentina
Rx only

FORMULA
Each coated tablet of MOSAR 5 mg contains: Mosapride citrate dihydrate 5.28 mg (equivalent to mosapride citrate 5 mg), Lactose monohydrate 102.457 mg, Pregelatinized starch 22.00 mg, Hydroxypropyl cellulose 6.75 mg, Croscarmellose sodium 9.75 mg, Magnesium stearate 1.50 mg, Hydroxypropyl methylcellulose 4.425 mg, Triacetin 2.40 mg, Titanium dioxide 0.675 mg, Colloidal silicon dioxide 2.25 mg.

INDICATIONS
For the treatment of:
-Non-ulcer dyspepsia,
-Gastrointestinal symptoms (heartburn, nausea, vomiting) accompanying chronic gastritis, -Symptoms and lesions associated with gastroesophageal reflux: heartburn, regurgitation, -Maintenance treatment of reflux esophagitis.

DOSAGE AND ADMINISTRATION
For oral use
Adults
Administer 15 mg mosapride citrate per day (3 tablets 5 mg), split into 3 doses before or after meals.
Children
There is no safety and effectiveness data in the administration in children.
Elderly
Pharmacokinetic profile of a single dose of mosapride 7.5 mg in elderly volunteers (aged 65–72 years) was generally similar to that in younger volunteers (aged 20–27 years). In elderly patients, different dosages are usually required.
However, it is appropriate to administer the drug with caution in patients with any degree of renal dysfunction, or if there is any side reactions. In such case, reduce the dose to 7.5 mg/day, split into 3 doses.

Renal impairment
In patients with severe renal impairment, the initial dose should not exceed 7.5 mg/day, or 2.5 mg, 3 times per day.
Pharmacokinetic data is unavailable for patients with renal impairment, but there is a potential for reduced clearance. Hence the drug should be administered with caution in such patients.
Hepatic impairment
In patients with severe hepatic impairment, the initial dose should not exceed 7.5 mg/day, or 2.5 mg, 3 times per day.
Pharmacokinetic data is unavailable for patients with hepatic impairment, but there is a potential for reduced clearance. Hence the drug should be administered with caution in such patients.

CONTRAINDICATIONS
Mosapride citrate is contraindicated in patients with:
-Prior hypersensitivity to mosapride,
-Gastrointestinal perforation, obstruction, or hemorrhage.

PRECAUTIONS AND WARNINGS
Patients with a history of cardiac diseases
There is a potential for increased risk of arrhythmias in patients with a history of cardiac disease, including heart failure, conduction defects, ventricular arrhythmias (including torsades de pointes) and electrolyte disturbances, particularly hypokalemia.
QT-interval monitoring is suggested during combined use with antiarrhythmics or with mosapride alone in these patients.

Liver function impairment
Pharmacokinetic data in patients with impaired liver function is unavailable. There is a potential for reduced clearance of mosapride.

Renal impairment
Pharmacokinetic data in patients with renal impairment is unavailable. There is a potential for reduced clearance of metabolites.

00-000000

Drug interactions
Agents that may prolong the QT-interval
Concurrent use with agents that may prolong the QT-interval (e.g., procainamide, quinidine, flecainide, sotalol, tricyclic antidepressants) and agents that may rapidly induce hypokalemia (e.g., furosemide) potentially enhances risk of arrhythmias, including torsades de pointes.

Pregnancy
Mosapride should only be used during pregnancy if the benefits justify the potential risks. The safety and efficacy of mosapride during human pregnancy have not been established.

Lactation
The degree to which mosapride is excreted into human milk is unknown. Women should therefore be advised to avoid breastfeeding while taking mosapride.

Fertility
There are no relevant data available.

Ability to perform tasks that require judgement, motor or cognitive skills
There is no relevant data available.

ADVERSE REACTIONS
Clinical Trial Data
Not relevant for this product.
Post Marketing Data
Adverse reactions are ranked under headings of frequency using the following convention:
Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known (cannot be estimated from the available data).
Nervous system disorders
Not known: headache
Gastrointestinal disorders
Not known: diarrhoea, dry mouth, nausea, abdominal pain
Hepatobiliary disorders
Not known: transaminases increased

Storage
Store at room temperature to 25°C.

Shelf life
As indicated on the outer packaging.

How Supplied
Coated tablets: Available in packs containing 4, 20, 25, 30, 40, 50 and 60 coated tablets.

Use and handling
There are no special requirements for use or handling of this product.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Incompatibilities
There are no relevant data available.

Laboratories
PHOENIX
Commitment to Health

Recyclable Material

Manufactured by: Laboratorios PHOENIX S.A.I.C. y F.
Calle (R202) Gral. Juan Gregorio Lemos 2809
(B1613AUE), Los Polvorines, Pcia. de Buenos Aires.
e-mail: info@phoenix.com.ar
Distributed in Lebanon by Droguerie Phenicia
Achrafieh-Chahrouri Street-Attallah Bldg., Beirut,
Lebanon. Certificate Nº 194340/05
NCDS Version number: 01
Version date: 31 January 2011

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

000000-00