Mosar Plus
Mosapride
Simethicone

Coated tablets

MADE IN ARGENTINA
Rx only

FORMULA
Each coated tablet contains:
Mosapride citrate dihydrate (equivalent to 5.00 mg of mosapride citrate) 5.28 mg.
Simethicone 50% (equivalent to 200 mg of simethicone) 400.00 mg.
Excipients: tricalcium phosphate 300.00 mg, colloidal silicium dioxide 30.00 mg, gelatin 5.00 mg, povidone 9.80 mg, anhydrous dibasic calcium phosphate 442.52 mg, copolyvidone 30.00 mg, yellow D&C N°10 shellac 1.293 mg, sunset yellow N°6 shellac 0.0535 mg, croscarmellose sodium 76.00 mg, hydroxipropylmethylcellulose 9.07 mg, diethylphtalate 0.65 mg, polyethylene glycol 6000 2.51 mg, titanium dioxide 4.47 mg, sodium saccharin 0.19 mg, sodium cyclamate 0.097 mg.

THERAPEUTIC ACTION
Antidyspeptic, antiflatulence, regulates digestive motility and accelerates gastric emptying.
ATC Code: A03FA.

INDICATIONS
Disorders associated with delayed gastric emptying (gastroparesis) associated with flatulence and meteorism.

PHARMACOLOGICAL PROPERTIES
Pharmacological action
Mosapride citrate
Mosapride citrate is a selective agonist of the serotonin 5-HT4 receptors present in the intrinsic nerves of the GI tract, and participates in the increased release of acetylcholine. For this reason it is thought to accelerate gastric emptying and modulate digestive motility both in the upper and lower intestinal tract.
Simethicone
Simethicone, a physiologically inert substance, has no pharmacological activity and acts by modifying the surface tension of the gas bubbles causing their coalescence and facilitating their removal.
Pharmacokinetics
Mosapride citrate
This medication is given orally and before food intake. After oral administration of mosapride citrate, the peak concentration is reached 0.8 hours after ingestion, and its maximum concentration is 30.7 ng / ml (Cmax = 30.7 ng / ml). The half-life is 2 hours. Mosapride citrate binds to plasma proteins by 99%. It is metabolized in the liver by cytochrome P450, particularly CYP3A4. The unchanged active substance and its major metabolite are excreted in the urine and faeces.

DOSAGE AND ADMINISTRATION
Adults
Give 1 tablet before meals, three times a day.
Geriatric patients
The dose may be reduced to 7.5 mg/day.

CONTRAINDICATIONS
Hypersensitivity to the active substance or any of its components. Pregnancy. Lactation. Children.

PRECAUTIONS AND WARNINGS
The product should be used with caution in patients with hepatic and/or renal impairment.
A dosage adjustment should be considered in geriatric patients.
Mosapride citrate
If, despite the administration of medication, an improvement of the digestive symptoms that accompany chronic gastritis is not observed during a prolonged period (usually 2 weeks), the administration should not be continued.
Simethicone
There are clinical trials in a population between 2 and 92 years, with treatment duration of up to 2 years in a row with good tolerance; however, maximum treatment duration of 15 days in a row is recommended. If symptoms persist after this time, the clinical situation should be reviewed.

Drug interactions
Mosapride citrate
Caution with concomitant use

Name of medication	Clinical symptoms • Method of administration	Mechanism • Risk factor
Anticholinergic agents: Atropine Butylscopolamine	As it can decrease the action of this drug, if an anticholinergic agent is given, due care must be taken, for example, to increase the intervals of administration.	The accelerating effect on GI motility of this drug is a manifestation of the activation of cholinergic motor nerves, so if an anticholinergic agent is added, the action of the drug is inhibited.

By associating mosapride with erythromycin, the maximum plasma concentration, the half-life and the AUC (area under the curve) of mosapride may increase, so caution should be exercised in this case.
Simethicone
Drug interactions have not been described.
Carcinogenesis, mutagenesis and fertility disorders
Mosapride citrate
In rodent studies, oral administration of 100 ~ 330 times the usual clinical dose (30 to 100 mg / kg / day) for a long period (rats: 104 weeks, mice 92 weeks) confirmed an increase in the rate of appearance of tumors (liver cell adenoma and follicular thyroid tumor).
Simethicone
The safety margin is very high. Due to the lack of digestive absorption of simethicone, it is physiologically inert and considered as nontoxic.
Pregnancy
Assess the potential risk / benefit of the drug on pregnancy before using.
Mosapride citrate
In women who are or might be pregnant, administer only if the utility of treatment outweighs the risk of it. (Safety with respect to the administration during pregnancy is not confirmed).
Simethicone
Simethicone belongs to the FDA (Food and Drug Administration of the United States) category C.
There is no evidence of injury in pregnant women due to lack of digestive absorption of simethicone by the mother.
Lactation
Assess the potential risk / benefit of the drug before using.
Mosapride citrate

Avoid administration in women who are breastfeeding, but if the administration is essential, stop breastfeeding. In experimental animals (rats), the passage of the drug into breast milk was reported.
Simethicone
It is not known whether this drug is excreted in human milk; however, excretion is not expected due to a lack of digestive absorption of simethicone by the mother. Its use is generally accepted.

Pediatric use
Safety has not been studied in this population.
Mosapride citrate
Safety has not been established in administration to children. (There is no experience with its use).
Simethicone
The dosage must be individualized on the basis of the seriousness of the situation and on the surface of the patient rather than the weight.

Geriatric use
Mosapride citrate
As the physiological functions of kidney and liver are impaired in general in the elderly, administer medication cautiously observing the patient's condition. If side effects occur when used for digestive symptoms that accompany chronic gastritis, lower the dose (i.e. 7.5 mg per day) and take appropriate action.

ADVERSE REACTIONS
Mosapride citrate
The main adverse reactions were diarrhea, loose stools (1.8%), dry mouth (0.5%), and asthenia (0.3%). Abnormal changes were seen in clinical test values: eosinophilia (1.1%) neutral fats increase (1.0%), increased SGOT, SGPT, alkaline phosphatase and γ-GT (each 0.4%) . After marketing, according to research results for use and special investigations (investigations of long-term use), the following adverse reactions were observed: diarrhea, loose stools (0.8%), abdominal pain (0.4%), dry mouth (0.3%) (at the end of the re-research).

Significant adverse effects
Fulminant hepatitis, abnormal liver function, jaundice (all less than 0.1%).
In fulminant hepatitis there is a severe impairment of liver function leading to a marked increase in GOT, GPT and γ-GTP, in addition to jaundice, and even fatal cases, therefore, it is recommended to observe cautiously, and if any change is confirmed immediately suspend administration and take appropriate action.

Other adverse effects

Classification	0.1~ less than 2%	Less than 0.1%	Uncertain frequency
Hypersensitivity effects.		Edema, urticaria.	Exanthema
Hematologic effects.	Eosinophilia.	Leukopenia.	
Gastrointestinal effects.	Diarrhea, loose stools, dry mouth, abdominal pain, nausea, vomiting.	Taste changes. Abdominal distension.	Numbness of the mouth (including tongue and lips).
Hepatic effects.	SGPT increase.	SGOT, alkaline phosphatase, γ-GT and bilirubin increase.	
Cardiovascular effects.		Palpitations.	
Neurological effects.		Vertigo, dizziness, headache.	
Other effects.	Adynamia, neutral fats increase.	Delirium tremens.	

The adverse effects of simethicone are usually mild and transient. The most characteristic adverse reaction is: rarely (<1%): moderate and transient constipation.
Belching may occur which is the normal mechanism of removing the gases with this treatment.

OVERDOSE
Simethicone
Cases of untreated overdose have not yet been reported.
Even if a much higher amount than that indicated is swallowed, it is highly unlikely that adverse effects appear due to the lack of digestive absorption of the drug.
In case of accidental or deliberate overdose, treat the symptoms that appear. No special procedure is recommended.

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

Storage
Store below 25 °C.

HOW SUPPLIED
Available in packs containing 20, 30, 40, 50, 60, 500 and 1000 coated tablets, the last two being exclusive presentations for hospital use.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Manufactured by Laboratorio Elea Phoenix S.A.,
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"The sale package of this product has its trade name printed in Braille, in order to allow its identification by blind patients".

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