

SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

MOXYDAR, tablet for oral suspension

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Hydrated aluminium oxide	500.0 mg
Magnesium hydroxide	500.0 mg
Hydrated aluminium phosphate	300.0 mg
Coated guar gum	200.0 mg
Quantity equivalent to guar gum	198.0 mg

For a tablet weighing 1.565 g

For the full list of excipients, see the section "List of excipients".

PHARMACEUTICAL FORM

Tablet for oral suspension.
White tablet of 20 mm in diameter

CLINICAL PARTICULARS

Therapeutic indications

Symptomatic treatment for pain linked to oesophago-gastro-duodenal disorders.
Symptomatic treatment of gastro-oesophageal reflux.

Posology and method of administration

Oral route.

Put the tablet in a glass of water. After complete disintegration of the tablet, shake the suspension a few moments then ingest the obtained suspension. Rinse possibly the glass with a little water and ingest again.

- Symptomatic treatment for pain linked to oesophago-gastro-duodenal disorders

One tablet if painful attacks occur, without exceeding 4 doses per day.

- Symptomatic treatment of gastro-oesophageal reflux

- During the loading period: 1 tablet 1 hour after each of the 3 meals and 1 additional tablet if pain occurs, for 4 to 6 weeks;
- For maintenance treatment: 1 tablet if pain occurs.

Contraindications

Related to magnesium: severe renal failure.

Hypersensitivity to the active substances or to any of the excipients mentioned in the section "List of excipients".

Special warnings and precautions for use

Precautions for use

In renal failure patients and chronic dialysis patients, take into account the aluminium content (risk of encephalopathy).

Interactions with other drugs and other forms of interaction

An interval of 2 hours must be observed between the intake of this medicine and administration of other medicines such as: salicylic acid, H2 antihistaminic, lansoprazole, bisphosphonates, cationesins, some antibiotics (fluoroquinolones, cyclins, lincosanides), digitalics, glucocorticoids, thyroid hormones, thiazides' diuretics and related drugs, phenothiazine's neuroleptics, sulpiride, some beta-blockers, penicillamine, ions (iron, phosphor, fluorine), zinc, strontium, chloroquine, dolutegravir, elviteravir, fexofenadine, ledipasvir, rosuvastatine, teriflunomide, ulipristal, estramustine.

Pregnancy and breast-feeding

There are no reliable teratogenicity data in animals.

In clinical use, there are to date insufficient pertinent data to assess the possible malformative or foetotoxic effect of aluminium or magnesium hydroxides when they are administered during pregnancy.

Taking into account its poor absorption, this medicinal product is only to be used during pregnancy if necessary

Take into account the presence of aluminium and magnesium ions likely to have an impact on transit:

- aluminium salts cause constipation, which may be additional to that classically experienced during pregnancy.

- magnesium salts may induce diarrhoea.

Try to restrict the daily dose and, if possible, and the duration of intake of this medicinal product.

Effects on the ability to drive and use machines

Moxydar has no effect or an insignificant effect on the ability to drive and use machines.

Undesirable effects

Transit disorders (diarrhoea and constipation).

Related to aluminium: phosphorous depletion in the event of prolonged use or high doses.

Reporting of suspected undesirable effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Agence nationale de sécurité du médicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.signalement-sante.gouv.fr

Overdose

High doses of aluminium may increase the risk of occurrence of phosphorous depletion, constipation or bowel obstruction.

Patients with renal failure may be at risk of hypermagnesemia.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: ANTACID – ATC code: A02AD01
(A: digestive system and metabolism)

In-vitro study (using the Vatier method):

- total antacid capacity (titration at pH 1) = 46.82 mmoles acid/dose.
- mechanism of action:
 - neutralising capacity (rise in pH) = 20%

- buffering potential (pH maintained around a fixed value) = 80% at pH 3.0 – 2.0
- theoretical protective capacity: from pH 1 to pH 3 = 31.57 mmoles of acid/dose.

Pharmacokinetic properties

Hydroxides of magnesium and aluminium are considered as local antiacids, non-systematic, whose absorption is negligible under normal conditions of use.

Preclinical safety data

No information is available.

PHARMACEUTICAL PARTICULARS

List of excipients

Sodium cyclamate, sodium saccharin, magnesium stearate, mint flavour *, simethicone, sorbitan oleate, polysorbate 80

* Composition of the mint flavour: essential oils of mint deterspenized and essential oils of mint atomised on an acacia gum backing.

Shelf life

3 years.

Special storage precautions

No special storage precautions are required.

Nature and contents of the container

30 tablets in blister (Aluminium/PVC).

Instructions for use and handling

Any unused product or waste material should be disposed of in accordance with current regulations.

MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

MARKETING AUTHORISATION NUMBER

34009 331 114 3 4: 30 tablets in blister (Aluminium/PVC)

DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION

22 June 1988/22 March 2009

DATE APPROVED/ REVISED

10 August 2017