SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

MOXYDAR, tablet for oral suspension

QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrated aluminium oxide	500.00 mg
Magnesium hydroxide	500.00 mg
Hydrated aluminium phosphate	300.00 mg
Coated guar gum	200.00 mg
Quantity equivalent to guar gum	198.00 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.

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

- Initial treatment: : 1 tablet after each of the 3 meals and 1 additional tablet if pain occurs, for 4 to 6 weeks;
- 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

In renal failure patients and chronic dialysis patients, take into account the aluminium content (risk of encephalopathy).
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

Interactions with other medicinal products and other forms of interaction

Combinations subject to precautions for use

Take antacids at a distance from other oral medications (more than 2 hours if possible).

+ Calcium polystyrene sulfonate or sodium polystyrene sulfonate:

Risk of metabolic alkalosis in renal failure.

+ Citrates:

Risk of facilitating the systemic passage of aluminum, especially in cases of impaired renal function.

+ Others:
Risk of decreased digestive absorption of the following drugs taken by mouth:

acetylsalicylic acid, alendronic acid, clodronic acid, etidronic acid, ibandronic acid, oxidronic acid, pamidronic acid, risedronic acid, tiludronic acid, zoledronic acid, alimemazine, atenolol, betamethasone, bictegravir, budesonide, chloroquine, chlorpromacyidin, chloflortetridine, chloflortetrine clindamycin, cortisone, cyamemazine, demeclocycline, dexamethasone, digoxin, dolutegravir, doxycycline, elvitegravir, enoxacin, ethambutol, famotidine, iron, fexofenadine, fluorine, fluphenazine, isoniazid, lansopothyvoxine, levofacycline, lansopothyincazine, levofothylroxine, lansopothyincazine, levofothylroxine , lymecycline, methylenecycline, methylprednisolone, metopimazine, metoprolol, minocycline, moxifloxacin, nizatidine, norfloxacin, ofloxacin, oxomemazine, oxytetracycline, pefloxacin, penicillamine, phosphorus, piperazine, pipotiazine, prednisolone, prednisone, proguanil, promethazine, propericiazine, propranolol, raltegravir, ranitidine, rosuvastatin, sulpiride, teriflunomide, tetracycline, thyroxines, tigecycline, tiratricol, triamcinolone, ulipristal

Association not recommended:

Raltegravir or Bictegravir: Decreased absorption of these substances.

Pregnancy and lactation

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 medicament 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

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.

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 deterpenized and essential oils of mint atomised on an acacia gum backing.

Shelf life

3 years.

Special precautions for storage

No special storage precautions are required.

Nature and contents of container

30 tablets in blister (Aluminium/PVC).

Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. .

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

02 December 2020