

SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

MOXYDAR, oral suspension in sachet

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Hydrated aluminium oxide	500.00 mg
Hydrated aluminium phosphate	300.00 mg
Magnesium hydroxide	500.00 mg
Coated guar gum	200.00 mg
quantity equivalent to: guar gum	198.20 mg

per 20-mL sachet.

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

PHARMACEUTICAL FORM

Oral suspension in sachet.

CLINICAL PARTICULARS

Therapeutic indications

Symptomatic treatment of pain related to oesogastroduodenal disorders.
Symptomatic treatment of gastro-oesophageal reflux.

Posology and method of administration

Oral route.

- Symptomatic treatment of pain related to oesogastroduodenal disorders

One sachet at the time of the painful episode without exceeding 4 intakes daily.

- Symptomatic treatment of gastro-oesophageal reflux
- Initial treatment: 1 sachet after each of the 3 meals and 1 additional sachet in the event of pain for 4 to 6 weeks;
- Maintenance treatment: 1 sachet at the time of pain.

Contra-indications

Related to magnesium: severe kidney failure.

Known hypersensitivity to active substances or to one of the ingredients of the product.

Special warnings and precautions for use

Precautions for use

In kidney failure patients and patients on chronic dialysis, take into account the aluminium concentration (risk of encephalopathy).

This medicine contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E 217) that can induce cutaneous reactions (possibly delayed).

Interactions with other medicinal products and other forms of interaction

Combinations requiring precautions for use:

As a precaution, antacids should be taken apart from other medicinal products. If possible, let an interval of more than 2 hours, with:

- Kayexalate (*oral route*): reduction in the ability of the resin to bind potassium with a risk of metabolic alkalosis in kidney failure patients.

Risk of decreased intestinal absorption of the following medicinal products:

- Antibacterials - antituberculotics (ethambutol, isoniazid) (*oral route*)
- Antibacterials - cyclines (*oral route*)
- Antibacterials - fluoroquinolones (*oral route*)
- Antibacterials - lincosamides (*oral route*)
- H2 antihistamines (*oral route*)
- Atenolol, metoprolol, propranolol (*oral route*)
- Chloroquine (*oral route*)
- Diflunisal (*oral route*)
- Digoxin (*oral route*)
- Bisphosphonates (*oral route*)
- Fexofenadine
- Sodium fluoride
- Glucocorticoids (*oral route*) (reported for prednisolone and dexamethasone)
- Indomethacin (*oral route*)
- Ketoconazole (*oral route*)
- Lansoprazole
- Phenothiazine neuroleptics (*oral route*)
- Penicillamine (*oral route*)
- Phosphates (*supplements*)
- Iron salts (*oral route*)
- Thyroxin

Combinations to be taken into account:

- Salicylates:

Increased renal excretion of salicylates by alkalinisation of the urine.

Fertility, pregnancy and breast-feeding

There are no reliable animal teratogenicity data.

In clinical practice, there are currently no sufficiently pertinent data enabling evaluation of the malformation-inducing or foetotoxic effect of aluminium and magnesium hydroxides when 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 limit the daily dose and, if possible, the duration of intake of this medicinal product.

Undesirable effects

Transit disorders (diarrhoea and constipation).

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

Related to presence of parahydroxybenzoates: urticaria.

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

ANTACID

(A: gastrointestinal system and metabolism)

In vitro study (Vatier's method):

- Total antacid capacity (titration at pH 1) = 46.82 mmol of acid/dose.

- Mechanism of action:

. neutralising capacity (pH elevation) = 20%

. buffering capacity (maintenance around a fixed pH) = 80% at pH 3.0-2.0.

- Theoretical protective capacity:

. from pH 1 to pH 3 = 31.57 mmol of acid/dose.

Pharmacokinetic properties

No information is available.

Preclinical safety data

No information is available.

PHARMACEUTICAL PARTICULARS

List of excipients

Bronopol, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), sodium cyclamate, saccharin sodium, mint flavour*, purified water.

*Composition of the mint flavour: essential oil of mint, menthol, menthyl acetate, propyleneglycol.

Shelf life

2 years.

Special precautions for storage

No special precautions for storage are required.

Nature and contents of container

20 mL in a single-dose sachet (polyester + aluminium + PE), box of 30.

Special precautions for disposal and other 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 NUMBERS

34009 349 041 8 9: 20 mL in a single-dose sachet (polyester + aluminium + PE); box of 30.

DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION

30 December 1998 /30 December 2013

10. DATE OF REVISION OF THE TEXT

10 August 2017

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription