SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

MOXYDAR, oral suspension in sachet

QUALITATIVE AND QUANTITATIVE COMPOSITION

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.

Excipient(s) with known effect:sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217)

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.

Posology

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.

Contraindications

Related to magnesium: severe kidney failure.
Hypersensitivity to the active substances or to any of the excipients listed in section **“List of excipients“.**

Special warnings and 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 allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) by sachet, that is to say essentially “sodium free”.

Interactions with other medicinal products and other forms of interactions

Combinations requiring precautions for use:
As a precaution, antacids should be taken away from other medicinal products administered by oral route (more than 2 hours,if possible).

+ CALCIUM POLYSTYRENE SULPHONATE or SODIUM POLYSTYRENE SULPHONATE
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 oral route:

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.

Fertility, pregnancy and lactation
Pregnancy

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 aluminum and magnesium hydroxides when administered during pregnancy.
Taking into account its low absorption, this medicinal product is only to be used during pregnancy if necessary.

Take into account the presence of aluminum 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 aluminum: phosphate depletion in the event of prolonged use or high doses.
Related to presence of parahydroxybenzoates: urticaria.

Reporting of suspected adversereactions:
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 aluminum 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

Pharmacotherapeutical group: ANTACID- ATC code: A02AD01

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.

PHARMACEUTICAL PARTICULARS

List of excipients
Simeticone, sorbitan oleate, polysorbate 80, 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

This medicine does not require any special storage conditions.

Nature and contents of container

20 mL in 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 local requirements.

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 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
06 October 2020

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription