# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**MOXYDAR, oral suspension in single-dose sachet.**

## 2. 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 single-dose sachet.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral suspension in single-dose sachet.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

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

### 4.2. 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.

### 4.3. Contra-indications

Related to magnesium: severe kidney failure.
Known hypersensitivity to active substances or to one of the ingredients of the product.

## 4.4. 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).

## 4.5. 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, leave 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.

## 4.6. Pregnancy and breast-feeding

There are no reliable animal teratogenicity data.
In clinical practice, there are currently insufficiently 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.

### 4.7. Effects on ability to drive and use machines

Not applicable.

### 4.8. 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 adverse reactions
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.ansm.sante.fr

### 4.9. 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.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. 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.

### 5.2. Pharmacokinetic properties

Not specified.

### 5.3. Preclinical safety data

Not specified.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. 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.

### 6.2. Incompatibilities

Not applicable.

### 6.3. Shelf life

2 years.

### 6.4. Special precautions for storage

No special precautions for storage.

### 6.5. Nature and contents of container

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

### 6.6. Method of use, instructions for handling

No special requirements.

## 7. MARKETING AUTHORISATION HOLDER

GRIMBERG Laboratories- 19 rue Poliveau- 75005 PARIS- France

## 8 PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

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

## 9. DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION

December 30, 1998

## 10. DATE OF REVISION OF THE TEXT

March 28, 2011

**11. DOSIMETRY:** Not applicable

**12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS:** Not applicable

## PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product not subject to medical prescription