SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MOXYDAR, tablet for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients
Aluminium oxide hydrate..... 500.0 mg
Magnesium hydroxide..... 500.0 mg
Aluminium phosphate hydrate ..... 300.0 mg
Coated guar gum * ..... 200.0 mg

For a tablet weighing 1.565 g

For the full list of excipients, see the section 6.1

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 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.

4.3 Contraindications

Related to magnesium: severe renal failure.
Hypersensitivity to the active substances or to one of excipients mentioned in the section 6.1

4.4 Special warnings and precautions for use

Precautions for use
In renal failure patients and people undergoing long-term dialysis, allow for the aluminium content (risk of encephalopathy).

4.5 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, catioresins, 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.

4.6 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.
In view of its low absorption, the use of this medicine should only be envisaged during pregnancy if necessary.

Take into account the inclusion of aluminium and magnesium ions that could affect transit:

- aluminium salts can induce constipation, which can occur in addition to that which often occurs during pregnancy.
- magnesium salts can induce diarrhoea.

Try to restrict the daily dose and, if possible, and the duration for which the medicine is taken.

4.7 Effects on the ability to drive vehicles and use machines

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

4.8 Adverse effects

Disorders affecting transit (diarrhoea and constipation).

Linked to aluminium: phosphorus depletion can occur during prolonged use or the administration of high doses.

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

Strong doses of aluminium can induce an increase of risk occurrence of phosphorous depletion, constipation and even intestinal obstruction.
Patients with renal failure may be at risk of hypermagnesemia.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ANTACID
(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.

5.2. Pharmacokinetic properties

Hydroxides of magnesium and aluminium are considered as the local antiacids, not systematic, the absorption of which is unimportant in the normal conditions of use.

5.3. Preclinical safety data

Not specified.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

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

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

6.2 Incompatibilities

Not applicable.

6.2 Shelf life

3 years.

6.3 Special storage precautions

This medicine does not require any special storage conditions.

6.4 Nature and contents of the container

30 or 60 tablets in blister (Aluminium/PVC).
Not all the pack sizes may be marketed.

6.5 Instructions for use and handling

No special requirements.

7. PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

34009 331 114 3 4: 30 tablets in blister (Aluminium/PVC)
34009 355 719 2 2: 60 tablets in blister (Aluminium/PVC)

8. PRESCRIPTION AND DISPENSING CONDITIONS

Medicinal product not subject to medical prescription

9. MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG
19, rue Poliveau
75005 PARIS
FRANCE

10. DATE APPROVED/ REVISED.

15.06.2016