

Package leaflet: Information for the user

MOXYDAR, tablet for oral suspension

Hydrated aluminium oxide, aluminium phosphate, magnesium hydroxide, coated guar gum

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

Keep out of the reach of children

In this leaflet:

1. WHAT MOXYDAR, tablet for oral suspension IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOXYDAR, oral suspension in a sachet
3. HOW TO TAKE MOXYDAR, tablet for oral suspension
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1. WHAT MOXYDAR, tablet for oral suspension IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group/ Antacid – ATC code: A02AD01

This medicine is indicated for pain, burning or sourness of the stomach or oesophagus and for the symptomatic treatment of gastro-oesophageal reflux.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOXYDAR, tablet for oral suspension

Do not use MOXYDAR, tablet for oral suspension:

- If you have a severe kidney failure (failure of kidney functions)
- if you are allergic (hypersensitive) to the active substances or any of the other ingredients of this medicine listed in section 6

Warnings and precautions

Talk to your doctor or pharmacist before taking MOXYDAR, tablet for oral suspension.

Special warnings

If disorders do not resolve in 7 days, you should consult your doctor.

If pain is associated with fever or vomiting, you should immediately consult your doctor.

Precautions for use

DO NOT TAKE THIS MEDICINE WITHOUT MEDICAL ADVICE in case of chronic dialysis.

Antacids can decrease the effects of numerous medicines. Always tell your doctor or pharmacist about any other ongoing treatment.

As a precaution, take this medicine remotely from other medicines (an interval of 2 hours if possible).

While using this medicine at the same time, it is recommended to observe certain hygiene and dietary rules:

- do not go to bed immediately after a meal,
- do not sleep flat (raise the head of the bed in order to decrease the frequency of night-time reflux),
- avoid prolonged work bending forward (housework, gardening, etc.),
- avoid excessively large meals.

Other medicines and MOXYDAR, tablet for oral suspension

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

This medicine will be used during pregnancy with medical advice only

If you discover that you are pregnant during the treatment, please consult your doctor because only a doctor can decide whether it is necessary to continue the treatment.

This medicine may be prescribed during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

MOXYDAR has no or negligible effect on ability to drive and use machines.

3. HOW TO TAKE MOXYDAR, tablet for oral suspension

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Posology

- *Symptomatic treatment of pain related to oesogastroduodenal disorders*

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

- *Symptomatic treatment of gastro-oesophageal reflux*

- Initial treatment: 1 tablet after each of the 3 meals and 1 additional tablet in case of pain for 4 to 6 weeks;
- Maintenance treatment: 1 tablet at the time of pain.

Method of administration

Oral route.

Put the tablet in a glass of water. After complete disintegration of the tablet, stir the suspension a few moments and then ingest the suspension. Rinse optionally the glass with a little water and ingest again.

Treatment duration

The duration of the treatment depends on the symptoms.

If you take more MOXYDAR, tablet for oral suspension than you should:

Consult your doctor or pharmacist immediately.

If you forget to take MOXYDAR, tablet for oral suspension

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- constipation / diarrhoea,
- reduction in the blood phosphorus concentration in case of prolonged use or high doses.

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: National Agency for safety of medicines and health products (ANSM) and network of the Regional Centers of Pharmacovigilance. Web site: www.signalement-sante.gouv.fr. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MOXYDAR, tablet for oral suspension

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the cardboard box. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What MOXYDAR, tablet for oral suspension contains

- The active substances are:

Hydrated aluminium oxide	500.0 mg
Hydrated aluminium phosphate	300.0 mg
Magnesium hydroxide	500.0 mg
Coated guar gum	200.0 mg
quantity equivalent to guar gum	198.2 mg

Per one tablet of 1.565 g

- The other ingredients are:

Sodium cyclamate, sodium saccharin, magnesium stearate, mint flavour*, Simeicone, sorbitan oleate, polysorbate 80.

*Composition of mint flavour: deterpenated essential oils of mint, atomised essential oils of mint on a medium of acacia gum

What MOXYDAR, tablet for oral suspension looks like and contents of the pack

This medicine is a tablet for oral suspension. Box of 30 tablets.

Marketing Authorisation Holder:

LABORATOIRES GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

Manufacturer:

Laboratoires GRIMBERG SA - ZA des Boutries - rue Vermont - 78704 Conflans Sainte Honorine cedex - France

This leaflet was last revised in August 2017.

Detailed information on this medicinal product is available on ANSM website (France)