

Package leaflet: Information for the user

MOXYDAR, oral suspension in sachet

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 after 7 days.

What is in this leaflet:

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

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOXYDAR, oral suspension in sachet?

Do not use MOXYDAR, oral suspension in sachet:

- in case of 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, oral suspension in sachet.

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

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 (more than 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, oral suspension in sachet

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

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
This medicine will be used during pregnancy with medical advice only.

Breast-feeding

This medicine may be prescribed during breast-feeding.

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

MOXYDAR, oral suspension in sachet contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) and sodium.

Sodium methyl parahydroxybenzoate (E 219) and sodium propyl parahydroxybenzoate (E 217) may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol (23 mg) of sodium per sachet, that is to say essentially "sodium-free".

3. HOW TO TAKE MOXYDAR, oral suspension in sachet?

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

Symptomatic treatment of pain related to oesogastroduodenal disorders

The recommended dose is one sachet at the time of the painful episode without exceeding 4 intakes daily.

Symptomatic treatment of gastro-oesophageal reflux

The recommended dose is:

Initial treatment: 1 sachet after each of the 3 meals and 1 additional sachet in case of pain for 4 to 6 weeks;

Maintenance treatment: 1 sachet at the time of pain.

Method of administration

Oral route.

Treatment duration

The duration of the treatment depends on the symptoms.

If you use more MOXYDAR, oral suspension in sachet than you should:

Consult your doctor or pharmacist immediately.

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.

If you forget to use MOXYDAR, oral suspension in sachet:

Do not take a double dose to make up for the dose you forgot.

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,
- due to the presence of parahydroxybenzoates, this medicine may induce urticaria.

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via your national reporting system.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MOXYDAR, oral suspension in sachet?

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 after EXP. 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 medicine 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, oral suspension in sachet contains?

The active substances are:

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 one sachet

The other ingredients are:

Simeticone, sorbitan oleate, polysorbate 80, bronopol, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), sodium cyclamate, sodium saccharin, mint flavor, purified water.

What MOXYDAR, oral suspension in sachet looks like and contents of the pack?

This medicine contains 20 ml oral suspension in sachet. Box of 30 sachets of 20 ml.

Marketing Authorisation Holder:

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Manufacturer:

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