

PACKAGE LEAFLET

MOXYDAR, oral suspension in single-dose sachet

Read all of this leaflet carefully before you start using this medicine. It contains important information for your treatment

If you have any further questions, if you have any doubt, ask your doctor or pharmacist

- . Keep this leaflet, you may need to read it again.
- . If you need further information and advice, please ask your pharmacist.
- . If symptoms worsen or persist, consult your doctor.
- . If you notice any side effects not listed in this leaflet or if any of the side effects gets serious, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT IS MOXYDAR, oral suspension in single-dose sachet AND WHEN IS IT USED?
2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING MOXYDAR, oral suspension in a single-dose sachet?
3. HOW TO USE MOXYDAR, oral suspension in single-dose sachet?
4. WHAT ARE THE POSSIBLE SIDE EFFECTS?
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6. FURTHER INFORMATION

1. WHAT IS MOXYDAR, oral suspension in single-dose sachet AND WHEN IS IT USED? ANTACID

(A: gastrointestinal system and metabolism)

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 IS THE INFORMATION TO BE AWARE OF BEFORE USING MOXYDAR, oral suspension in single-dose sachet?

Never use MOXYDAR, oral suspension in single-dose sachet:

- in case of severe kidney failure (failure of kidney functions)
- in case of known allergy to one of the ingredients of the product

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with MOXYDAR, oral suspension in single-dose sachet:

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.

This medicine contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate that may cause allergic reactions (possibly delayed).

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast feeding

This medicine will be used during pregnancy with medical advice only.

If you discover that you are pregnant during treatment, 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.

Excipients with known effect

Sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate.

3. HOW TO USE MOXYDAR, oral suspension in single-dose sachet ?

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 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 single-dose sachet than you should:

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.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?

Like all medicines, MOXYDAR, oral suspension in single-dose sachet 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.

Statement of the side effects:

If you feel any adverse effect, tell it to your doctor or your pharmacist or your nurse. This also applies to any adverse effect which would not be mentioned in this leaflet. You can also declare adverse effects directly via the national system of statement: the National Agency for safety of medicines and health products (Ansm) and the Regional Centers of Pharmacovigilance. The web site: www.ansm.sante.fr. By reporting the adverse events, you contribute to supply more information on the medicine safety.

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

Keep out of the reach and sight of children.

Do not use MOXYDAR, capsule, after the expiry date which is stated on the outer packaging. No special storage conditions.

Medicines should not be disposed of via waste-water or household wastes. Ask your pharmacist how to dispose of medicines no longer used. These measures will help protect the environment.

6. FURTHER INFORMATION

What does MOXYDAR, oral suspension in single-dose sachet contain ?

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 single-dose sachet

The other ingredients are:

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

What is MOXYDAR, oral suspension in single-dose sachet and contents of the outer pack ?

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

Marketing Authorisation Holder / Operating company: Laboratoires GRIMBERG - 19, rue Poliveau - 75005 Paris- France

Manufacturer:

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This leaflet was last approved on **28th March 2011**.