

PACKAGE LEAFLET

MOXYDAR, tablet for oral suspension

Read all of this leaflet carefully before you start using this medicine. It contains important information on 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.
- . This medicine has been prescribed for you personally. Never pass it on to others. It may harm them, even if their symptoms are the same as yours
- . 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, tablet for oral suspension and when is it used?
2. What is the information to be aware of before using MOXYDAR?
3. How to use MOXYDAR, tablet for oral suspension?
4. What are the possible side effects?
5. How to store MOXYDAR?
6. Further information

1. WHAT IS MOXYDAR, tablet for oral suspension 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, tablet for oral suspension?

Never use MOXYDAR, tablet for oral suspension

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

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

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.

IF IN DOUBT, 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 must only be used during pregnancy with medical advice. 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.

In general, it is recommended to ask your doctor or pharmacist always for advice before taking any medicine during pregnancy or breast-feeding.

Effects on ability to drive or use machines:

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

3. HOW TO USE MOXYDAR, tablet for oral suspension?

Posology

Always observe the dosage recommended by your doctor. In case of doubt, contact your doctor or pharmacist.

The usual dose is:

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. Optionally rinsing the glass with a little water and ingest again.

Treatment duration

Treatment duration depends on the symptoms.

If you use more MOXYDAR, tablet for oral suspension than you should

Consult your doctor or pharmacist immediately

If you forget to use MOXYDAR, tablet for oral suspension

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

If you have further questions about the use of this medicine, ask your doctor or pharmacist for further information.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, MOXYDAR, tablet for oral suspension can cause side effects, although not everybody gets them.

The following effects were reported:

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

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.anism.sante.fr. By reporting the adverse events, you contribute to supply more information on the medicine safety.

5. HOW TO STORE MOXYDAR, tablet for oral suspension?

Keep out of the reach and sight of children.

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

This medicine does not require any 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, tablet for oral suspension 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
Amount corresponding to the guar rubber.....	198,20 mg

For one tablet of 1,565 g

The other ingredients are:

Simeticone, sorbitan oleate, polysorbate 80, sodium cyclamate, sodium saccharin, magnesium stearate, mint flavor.

What is MOXYDAR and contents of the outer pack?

This medicine is a tablet for oral suspension. Box of 30 tablets or of 60 tablets.
All the pack-sizes may not be marketed.

Marketing Authorisation Holder/Operating company:

Laboratoires GRIMBERG
19, rue Poliveau
75005 PARIS – France

Manufacturer:

Laboratoires GRIMBERG
ZA des Boutries
5, rue Vermont
78700 CONFLANS SAINTE HONORINE – France

This leaflet was last approved on **2016, 06,15**.