

PACKAGE LEAFLET: INFORMATION FOR THE USER

Laxodal 7.5 mg/ml Oral Solution
Sodium Picosulfate

Read this leaflet carefully before you start taking this medicine, as it contains important information for you.

Take this medicine exactly as described in this leaflet, or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- If you need clarification or advice, please consult your pharmacist.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist.

What's in this leaflet:

1. What Laxodal is and what it is used for
2. What you need to know before you take Laxodal
3. How to Take Laxodal
4. Possible undesirable effects
5. How to store Laxodal
6. Contents of packaging and other information

1. What Laxodal is and what it is used for

Laxodal is a contact laxative. It is used in all forms of constipation.
It is presented in a dropper bottle containing 30 ml of Oral Solution.

2. What you need to know before you take Laxodal

Do not take Laxodal:

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Laxodal

Take special care with Laxodal in the following situations:

- Intestinal obstruction;
- Care during breastfeeding;
- Risks of prolonged use;
- Overdosage;
- Fluid and electrolyte deficit (risks in children and the elderly).

As with all laxatives, Laxodal should not be taken for long periods of time. If laxatives are found to be needed on a daily basis, the cause of constipation should be investigated. Prolonged or excessive use can lead to the appearance of a fluid and electrolyte imbalance and hypokalemia and can precipitate the appearance of constipation as a rebound effect.

Other medicines and Laxodal

Tell your doctor or pharmacist if you are taking or have recently taken or if you take any other medicines.

Concomitant use of diuretics or adrenocorticosteroids with high doses of Laxodal may increase the risk of electrolyte imbalance, which may lead to increased sensitivity to cardiac glycosides.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Long experience of the use of sodium picosulfate has not revealed the existence of undesirable effects during pregnancy. However, as with all drugs, Laxodal should only be given during pregnancy if advised by the doctor.

Although there is no evidence that Laxodal passes into breast milk, breastfeeding is not recommended.

Driving and using machines

There are no known effects on the ability to drive and use machines.

This medicine contains methyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

This medicinal product contains sorbitol (1 ml solution contains 390 mg sorbitol, corresponding to 0.39 g sorbitol per maximum recommended daily dose, for adults and children over 10 years of age). Sorbitol is a source of fructose. If your doctor told you that you have (or your child has) an intolerance to some sugars or if it was you are diagnosed with hereditary fructose intolerance (IHF), a rare genetic disorder in which a person cannot digest fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to Take Laxodal

Take this medication exactly as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children over 10 years: 10-20 drops (5-10 mg)

Children 4–10 years: 5–10 drops (2.5–5 mg)

Children under 4 years: 0.250 mg/kg body weight

Administer orally, diluted in a small quantity of water.

Children should not use Laxodal without medical advice.

If you take Laxodal more than you should

Symptoms

When given in high doses, Laxodal may cause watery stools (diarrhoea), abdominal cramps and a clinically significant depletion of potassium and other electrolytes.

In addition, cases of ischemia of the colonic mucosa have been reported in association with high doses of sodium picosulphate (considerably higher than the doses usually recommended for the treatment of constipation).

Laxatives are known to cause, in chronic overdose, chronic diarrhoea, abdominal pain, hypokalaemia, secondary hyperaldosteronism and kidney stones. Associated with laxative abuse have also been described, secondary to hypokalemia, renal tubule damage, metabolic alkalosis and muscle weakness.

Treatment

Absorption of the drug can be prevented or minimised if vomiting is induced shortly after ingestion or gastric lavage is performed. Fluid replacement and correction of electrolyte balance may be necessary. This is particularly important for elderly and young patients.

The administration of antispasmodics may be of some value.

If you forget to take Laxodal

If you forget to take Laxodal, take it as soon as you remember, on the same day, do not take a double dose to make up for the one you missed.

Stop taking Laxodal

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

4. Possible undesirable effects

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

Rare and minor occurrences (abdominal pain, nausea, vomiting and lipothymia) may occur and are easily eliminated by dose adjustment.

Reporting of undesirable effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your pharmacist. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>

(preferentially)

or through the following contacts:

Directorate of Drug Risk Management

Parque da Saúde de Lisboa, Av. Brazil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Drug Line: 800222444 (free of charge)

E-mail: farmacovigilancia@infarmed.pt

5. How to store Laxodal

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

The product should be kept at room temperature of 25°C and protected from light.

Do not use this medicine after the expiry date which is stated on the bottle and carton after the expiry date. The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Laxodal contains

- The active substance is Picosulfate sodium, it contains 7.5 mg per 1 ml of solution.

The other components are:

- Methylparaben (sodium), Sorbitol, Water

What Laxodal looks like and contents of the pack

It is an Oral Solution, presented in a dropper bottle containing 30 ml of solution.

Marketing Authorization Holder and Manufacturer

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