

Package Leaflet: Information for the Patient

Regulax[®] Picosulfate Oral Drops

7.23 mg/ml

Oral drops, solution

Active substance: sodium picosulfate

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.

What is in this leaflet

1. What Regulax[®] Picosulfate Oral Drops are and what they are used for
2. What you need to know before you take Regulax[®] Picosulfate Oral Drops
3. How to take Regulax[®] Picosulfate Oral Drops
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT REGULAX[®] PICOSULFATE ORAL DROPS ARE AND WHAT THEY ARE USED FOR

Regulax[®] Picosulfate Oral Drops are a laxative.

Regulax[®] Picosulfate Oral Drops are used for constipation and disorders which require easier passage of stools.

Like other laxatives, Regulax[®] Picosulfate Oral Drops should not be taken daily or over a prolonged period without a medical assessment of the cause of constipation.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE REGULAX[®] PICOSULFATE ORAL DROPS

Do not take Regulax[®] Picosulfate Oral Drops

- if you are allergic to sodium picosulfate, related active substances from the triarylmethane group or any of the other ingredients of this medicine (listed in section 6);

- if you have narrowing of the intestines with impaired bowel passage, bowel obstruction, acute abdominal complaints such as appendicitis, severe abdominal pain associated with nausea and vomiting;
- if you have an acute inflammatory disease of the gastrointestinal tract;
- if you are severely dehydrated.

Children below 4 years of age must not take Regulax[®] Picosulfate Oral Drops.

Constipation associated with other complaints, such as abdominal pain, vomiting and fever may be a sign of serious illness (bowel obstruction, acute abdominal inflammation). If such complaints occur, you must not take Regulax[®] Picosulfate Oral Drops or other medicines and you should consult your doctor immediately.

If you have an illness associated with fluid and electrolyte imbalance (e.g. severely impaired kidney function), you may only use Regulax[®] Picosulfate Oral Drops under medical supervision.

Warnings and precautions

Talk to your doctor or pharmacist before taking Regulax[®] Picosulfate Oral Drops.

- Children aged 4 years and older should take Regulax[®] Picosulfate Oral Drops only if their doctor tells them to.

- if your symptoms have occurred spontaneously, persist over a prolonged period of time and/or are accompanied by symptoms such as bloody stools or fever. In this case you should seek advice from your doctor before starting treatment with Regulax[®] Picosulfate Oral Drops and have yourself examined, as disorders or impaired bowel movement may be signs of a serious disease.

Regulax[®] Picosulfate Oral Drops should not be taken daily on a continuous basis or over prolonged periods without being evaluated by a doctor first.

Symptoms may reappear when Regulax[®] Picosulfate Oral Drops are discontinued. After long-term use in chronic constipation, the return of symptoms may also be associated with worsening constipation.

In patients who have taken sodium picosulfate, dizzy spells and brief bouts of unconsciousness (syncope) have been reported. Based on the relevant case reports, these cases of syncope are probably due to the laxative process itself, to straining or to circulatory reactions due to abdominal pain.

Other medicines and Regulax[®] Picosulfate Oral Drops

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

Antibiotics (medicines to treat bacterial infections), if taken at the same time, may result in a loss in the laxative effect of Regulax[®] Picosulfate Oral Drops.

With excessive use of Regulax[®] Picosulfate Oral Drops there is a risk of an imbalance of potassium and other salts in the blood. If you are also taking other medicines (e.g. water tablets [diuretics] or adrenal cortex hormones [corticosteroids]), this risk may be increased. This can lead to disorders of heart function and muscle weakness and may increase sensitivity to certain medicines to strengthen heart function (cardiac glycosides).

Pregnancy and breast-feeding

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.

Pregnancy

There are no meaningful clinical studies on use during pregnancy. You should avoid using this medicine as much as possible during pregnancy.

Breast-feeding

It has been shown that the active substance is not excreted in human milk. Regulax[®] Picosulfate Oral Drops can therefore be used during breast-feeding.

Driving and using machines

Normally, no adverse effects are to be expected when Regulax[®] Picosulfate Oral Drops are used at the specified dosage. However, should symptoms such as dizziness, brief loss of consciousness (syncope) or abdominal cramps occur, the ability to drive and use machines may be impaired.

Regulax[®] Picosulfate Oral Drops contain sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Regulax[®] Picosulfate Oral Drops.

3. HOW TO TAKE REGULAX[®] PICOSULFATE ORAL DROPS

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.

Unless otherwise prescribed by a doctor, the recommended dose for adults and adolescents is:

14 - 27 drops (equivalent to 5 - 10 mg sodium picosulfate).

Children aged 4 years and older should, if prescribed by a doctor, take a single dose of 7 - 14 drops (equivalent to 2.5 - 5 mg sodium picosulfate).

Method of administration:

Regulax[®] Picosulfate Oral Drops are preferably taken in the evening. The drops can be taken with or without liquids. The laxative effect normally occurs after 10 to 12 hours.

Please take into account the time to onset of action and do not try to force a bowel movement by intense straining.

Duration of use:

Regulax[®] Picosulfate Oral Drops should not be taken daily on a continuous basis or over prolonged periods without prior medical assessment.

Please talk to your doctor or pharmacist if you have the impression that the effect of Regulax[®] Picosulfate Oral Drops is too strong or too weak.

If you take more Regulax[®] Picosulfate Oral Drops than you should

Acute overdose of Regulax[®] Picosulfate Oral Drops can lead to diarrhoea, abdominal discomfort, loss of fluid, potassium and other minerals. Measures to treat an overdose are guided by the symptoms. Within a short while after taking the drops, the effect of the medicine can be reduced or prevented by induced vomiting or gastric lavage (stomach pumping). Heavy fluid and mineral losses should be corrected on the instructions of a doctor. Administration of antispasmodic medications may be useful in some cases.

Furthermore, isolated cases of reduced or interrupted blood flow through the colon lining have been reported, in which the sodium picosulfate dosage was much higher than the dosage recommended for treating constipation.

Note:

In general, Regulax[®] Picosulfate Oral Drops - like other laxatives in the event of chronic overdose - are known to cause chronic diarrhoea, abdominal pain, low potassium levels, excessive secretion of aldosterone and kidney stones. In association with chronic laxative misuse, there have also been reports of damage to kidney tissue, a metabolic increase in base concentrations in the blood, as well as muscle weakness caused by low potassium levels.

4. POSSIBLE SIDE EFFECTS

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

The following categories are used for stating the frequency of side effects:

Very common: more than 1 in 10 patients treated
Common: 1 to 10 patients treated out of 100
Uncommon: 1 to 10 patients treated out of 1,000
Rare: 1 to 10 patients treated out of 10,000
Very rare: less than 1 in 10,000 patients treated
Not known: cannot be estimated from the available data

Possible side effects:Immune system disorders

Frequency not known: allergic reactions (including skin reactions and swelling of the skin and/or mucous membranes [angioedema], e.g. in the face and throat region, possibly with shortness of breath).

Nervous system disorders

Uncommon: dizziness.

Frequency not known: brief loss of consciousness (syncope).

The information available indicates that these symptoms are due to severe straining during bowel movements or a circulatory reaction caused by pain in the lower abdomen (see section 2 “Warnings and precautions”).

Gastrointestinal disorders

Very common: diarrhoea.

Common: flatulence, abdominal pain or abdominal cramps.

Uncommon: nausea, vomiting.

If used incorrectly (for too long, at too high a dosage), Regulax[®] Picosulfate Oral Drops can lead to a loss of water, potassium and other electrolytes. This may cause heart dysfunction and muscle weakness, especially if water tablets (diuretics) or adrenal cortex hormones (corticosteroids) are taken concomitantly.

What to do if you are affected by side effects

If side effects occur, you should stop taking Regulax[®] Picosulfate Oral Drops and consult your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE REGULAX[®] PICOSULFATE ORAL DROPS

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 carton and label after “EXP”. The expiry date refers to the last day of that month.

Note on shelf life after opening

Once opened, Regulax[®] Picosulfate Oral Drops can be used for 6 months.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Regulax[®] Picosulfate Oral Drops contain:

The active substance is: sodium picosulfate.

1 ml solution (= 20 drops) contains 7.5 mg sodium picosulfate monohydrate (equivalent to 7.23 mg sodium picosulfate).

The other ingredients are:

Sorbitol solution 70% (non-crystallising) (Ph.Eur.), propylene glycol, purified water.

Advice for diabetics:

Suitable for diabetics: contains sugar substitutes; 1 ml is equivalent to 0.03 BU.

What Regulax[®] Picosulfate Oral Drops look like and contents of the pack

Regulax[®] Picosulfate Oral Drops are a clear, colourless oral solution.

Regulax[®] Picosulfate Oral Drops are available in packs of 20 ml (N1) and 50 ml (N3).

Marketing Authorisation Holder

Krewel Meuselbach GmbH
Krewelstr. 2
D-53783 Eitorf
Tel.: +49 (0)2243 / 87-0
Fax: +49 (0)2243 / 87-175
E-mail: info@krewelmeuselbach.de

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Properties

Bowel sluggishness and constipation are widespread complaints. However, they are only rarely caused by serious illness. In fact, they are mostly caused by aspects of everyday life, such as stress, lack of exercise, unfamiliar toilets and poor nutrition. Therefore, a good laxative should simply help you, without any stress.

With Regulax[®] Picosulfate Oral Drops, you have chosen a medicine that regulates bowel activity by increasing the volume of stools and stimulating peristalsis (natural, rhythmic movement of the bowel). In this way, bowel evacuation is regular yet gentle.

Also, try to find a well-balanced lifestyle pattern and reduce your dose of Regulax[®] Picosulfate Oral Drops at the same time. This will allow your bowel to return to normal, regular activity.

The following tips will help retrain your bowel to gain its normal function:

Try to make your life less hectic. It is best to go to the toilet unhurriedly at the same time each day, preferably at home in a familiar environment.

Make time for regular meals and go for a balanced, low-calorie diet with a high fibre content. Replace canteen food with fruit, salads and muesli.

Cut out high-calorie snacks. Drink more instead, e.g. mineral water.

Most professions curb our movement. However, a lack of exercise is one of the causes of constipation. Try to walk as much as possible or work out at the gym.

Also, remember that the medicine does not start to take effect until about 10 - 12 hours after taking a dose and that, for some people, emptying the bowel just twice or three times a week is quite normal.