

Package Leaflet: Information for the Patient

Regulax® Picosulfate Laxative Cubes

10 mg cubes

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 Laxative Cubes are and what they are used for
2. What you need to know before you take Regulax® Picosulfate Laxative Cubes
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1. WHAT REGULAX® PICOSULFATE LAXATIVE CUBES ARE AND WHAT THEY ARE USED FOR

Regulax® Picosulfate Laxative Cubes are a laxative.

Regulax® Picosulfate Laxative Cubes are used for constipation and disorders which require easier passage of stools.

Like other laxatives, Regulax® Picosulfate Laxative Cubes 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 LAXATIVE CUBES

Do not take Regulax® Picosulfate Laxative Cubes

- 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.

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 Laxative Cubes 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 Laxative Cubes under medical supervision.

Warnings and precautions

Talk to your doctor or pharmacist before taking Regulax® Picosulfate Laxative Cubes.

Children and adolescents

Children should take sodium picosulfate only if their doctor tells them to (see 3. "How to take Regulax® Picosulfate Laxative Cubes").

- 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 Laxative Cubes and have yourself examined, as disorders or impaired bowel movement may be signs of a serious disease.

Regulax® Picosulfate Laxative Cubes 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 Laxative Cubes 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 Laxative Cubes

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 Laxative Cubes.

With excessive use of Regulax® Picosulfate Laxative Cubes 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 Laxative Cubes can therefore be used during breast-feeding.

Driving and using machines

Normally, no negative impact is to be expected when Regulax® Picosulfate Laxative Cubes 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 Laxative Cubes contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Regulax® Picosulfate Laxative Cubes.

3. HOW TO TAKE REGULAX® PICOSULFATE LAXATIVE CUBES

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:

½ - 1 cube (equivalent to 5 – 10 mg sodium picosulfate).

Younger children aged 4 years and older are given 2.5 to 5 mg sodium picosulfate on the express instructions of their doctor. For this, the medicine is available as a solution.

Method of administration:

For oral use.

The cube is well chewed and swallowed with plenty of water. The medicine must not be taken lying down.

Regulax® Picosulfate Laxative Cubes are preferably taken in the evening. 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 Laxative Cubes 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 Laxative Cubes is too strong or too weak.

If you take more Regulax® Picosulfate Laxative Cubes than you should

Acute overdose of Regulax® Picosulfate Laxative Cubes can lead to diarrhoea and 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 cubes, 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 Laxative Cubes - 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 Laxative Cubes 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 Laxative Cubes 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 LAXATIVE CUBES

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 outer carton after "EXP". The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 30 °C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Regulax® Picosulfate Laxative Cubes contain:

The active substance is: sodium picosulfate.

1 cube contains 10 mg sodium picosulfate.

The other ingredients are:

Plum jam, sweet virgin maize starch, propylene glycol, sucrose (sugar), hard fat, microcrystalline cellulose, sodium monohydrogen phosphate dodecahydrate, glycerol monostearate, lemon aroma concentrate, fig flavouring.

What Regulax® Picosulfate Laxative Cubes look like and contents of the pack

Regulax® Picosulfate Laxative Cubes are brown cubes with a fruity odour.

Regulax® Picosulfate Laxative Cubes are available in packs of 6 cubes and 12 cubes (N1).

Marketing Authorisation Holder

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This leaflet was last revised in November 2013.

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 Laxative Cubes, 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 Laxative Cubes 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.