

PATIENT INFORMATION LEAFLET

SUPOLAKS 5 mg suppository For rectal use.

- **Active substance:** Each suppository contains 5 mg bisacodyl.
- **Excipient:** Witepsol H15.

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use higher or lower doses than the dose which was recommended for you.*

What is in this leaflet:

1. *What SUPOLAKS is and what it is used for?*
2. *What you need to know before you use SUPOLAKS?*
3. *How to use SUPOLAKS?*
4. *Possible side effects*
5. *How to store SUPOLAKS?*

1. What SUPOLAKS is and what it is used for?

- SUPOLAKS is presented as an almost white, homogeneous (uniform) looking suppository.
- SUPOLAKS is presented in a cardboard box containing 5, 10 or 20 suppositories.
- Each suppository contains 5 mg of active ingredient (bisacodyl). Bisacodyl belongs to the contact laxatives drug group.
- SUPOLAKS is used as a stimulant laxative (diarrhea) in the treatment of constipation.
- SUPOLAKS is used for bowel evacuation before surgery or research procedures such as x-rays and for all indications, instead of laxatives and enemas.

2. What you need to know before you use SUPOLAKS?

DO NOT use SUPOLAKS

If;

- you are allergic (hypersensitive) to the active substance or any of the excipients in its composition
- you have excessive water loss
- you have an intestinal obstruction (called ileus)
- you have serious abdominal discomfort such as appendicitis
- you have abdominal pain along with nausea and vomiting

- there is an inflammatory condition in the intestine
- you have severe heart failure
- you have cracks, wounds and inflammation around the anus

Warnings and precautions

- It should be kept in mind that prolonged use may cause bowel laziness and disturbance of water-electrolyte balance. Particular care should be taken in elderly patients and patients with renal insufficiency.
- It should not be administered to patients with intestinal obstruction or patients with undiagnosed intra-abdominal complaints and should be used with caution in inflammatory bowel diseases.
- It should not be used in patients with diabetes mellitus (diabetes), hypertension (increased blood pressure) and heart disease without consulting a doctor.
- The use of suppositories may cause pain sensation and local irritation (irritation at the application site), especially in patients with anal fissure (rectum crack) and ulcerative proctitis (inflammatory disease in the anus).
- It should not be used continuously for more than 5 days.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

SUPOLAKS with food and drink

It is not applicable due to the route of administration.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

Animal studies are insufficient. The potential risk for humans is unknown.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

It should not be used in nursing mothers.

Driving and using machines

It has no effect on the ability to drive or use machines.

You may feel dizziness or weakness while using this medicine. In such a case, avoid driving and using machines.

Important information about some of the excipients in SUPOLAKS

There is no special warning regarding the excipients contained in SUPOLAKS.

Other medicines and SUPOLAKS

It is especially important to tell your doctor if you are using any of the following medicines:

- Diuretics (such as bendrofluazide, furosemide)

- Steroid drugs (used in the treatment of inflammatory diseases, such as prednisolone)

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use SUPOLAKS?

- **Instructions for use and dosage/frequency of administration:**

For children aged 4-10: SUPOLAKS should be used with doctor's advice. Usually 5 mg of suppository is administered rectally (rectally) for immediate effect. Only 1 suppository is used per day.

It is used for bowel emptying before surgery, x-rays or other tests.

SUPOLAKS is used for a maximum of 5 days.

If the symptoms do not disappear or worsen within this period, consult a doctor.

It is intended for short-term use.

- **Route of administration and method:**

After the hands are thoroughly washed and dried, the suppository is applied by pushing into the anus and kept inside for at least 30 minutes.

This medicine is used for a maximum of 5 days. During this time, if your child's condition is getting worse or if new symptoms occur, you should stop the treatment immediately and consult your doctor or pharmacist.

- **Different age groups:**

Use in children:

SUPOLAKS should not be used in children under 4 years of age. It should be used with doctor's recommendation in children aged 4-10.

Use in elderly:

There is no specific information on use in the elderly. As a result of clinical studies conducted for over 65 years of age, no special adverse effects were found in this age group.

- **Special cases of use:**

Kidney/Liver failure:

There is no special use. Use in consultation with your doctor.

If you have impression that the effect of SUPOLAKS is very strong or weak, tell a doctor or pharmacist.

If you use more SUPOLAKS than you should:

As a result of the use of high doses, digestive system disorders such as abdominal pain (colic) and cramps can be seen suddenly in the form of seizures; bloating, low blood pressure, dizziness and diarrhea can be seen.

If you take more SUPOLAKS than you should, tell your doctor or pharmacist.

If you forget to use SUPOLAKS

Do not take a double dose to balance out the forgotten dose.

If you stop using SUPOLAKS

Not applicable.

4. Possible side effects?

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

If you notice any of the followings stop taking SUPOLAKS and immediately inform your doctor or go to the nearest emergency department:

- Severe allergic reactions to the face and throat
- Difficulty breathing or dizziness
- Allergic reactions that may cause skin rash

These are all very serious side effects.

If you have one of these, you have a serious allergy to SUPOLAKS. You may need an emergency medical intervention or hospitalization.

Side effects are classified according to frequency as follows:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

If you notice any of the followings, immediately inform your doctor or go to the nearest emergency department:

Common:

- Abdominal cramping and pain
- Diarrhea
- Nausea

Uncommon:

- Blood in stools
- Vomiting
- Abdominal discomfort
- Discomfort in and around the anus
- Dizziness

Rare:

- Inflammation of the large intestine
- Loss of water
- Fainting

All these are serious side effects. Emergency medical intervention may be required.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store SUPOLAKS?

Keep this medicine out of the sight and reach of children in its original package.

Store at room temperature below 25°C.

Use in accordance with expiry date.

Do not use SUPOLAKS after the expiry date which is stated on the package.

Do not use SUPOLAKS if you notice any damage to the product and/or package.

Marketing authorization holder:

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