



CONTALAX[®]

SUPPOSITORIES

Patient package insert in accordance with the
Pharmacists' Regulations (Preparations) 1986
Requires a doctor's prescription

The active ingredient and its quantity in a suppository:

Bisacodyl 10 mg.

None Active Ingredients and Allergens:

See section 6 "additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains a concise information about the medicine. For further information refer to your doctor or pharmacist. This medicine has been prescribed for you only. Do not give it to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children and infants under 6 years of age. This preparation is only intended for cases of constipation that have continued for a number of days. One or two days of intestinal inactivity do not justify its use. It should also not be used for the purpose of "internal body cleansing" and similar practices.

1. This medicine is prescribed for:

Relief of constipation. Therapeutic group: Laxatives.

2. Before using this medicine:

Do not use this preparation if

You are sensitive (allergic) to the active ingredient or to the other ingredients of this medicine. See section 6 "additional information" for other Ingredients. If you suffer from dehydration, bowel obstruction, Appendicitis, severe abdominal pain with nausea and vomiting, inflammatory bowel, anus fissure, inflammation or abscesses.

Special warnings relating to use of the medicine: Frequent or prolonged use of laxatives such as this may cause diarrhea as well as dependence. Don't use this medicine frequently or for prolonged periods without consulting a doctor or a pharmacist. Before using the medicine inform the attending doctor: If you suffer from a heart disfunction, if you are taking another drug concomitantly or if you have just finished treatment with another medicine, including non prescribed medicines and nutritional supplements. Especially if you take other laxatives or Diuretic drugs like furosemid or Steroids like Prednisolone.

If you are pregnant or nursing:

Before using the medicine, inform the doctor or the pharmacist if you are pregnant, planning a pregnancy or nursing.

Driving and using machinery:

If you feel dizzy or fainting while using the medicine, avoid driving or operating machinery until the feeling of dizziness or fainting disappears.

3. Directions for use:

Always use according to your doctor's instructions. If you are not certain, consult your doctor or pharmacist.

Only your doctor is permitted to determine the dosage and method of treatment. The customary dosage in general is: for adults and children above 10 years of age - one suppository (10 mg per day). For children 4-10 years old - half a suppository (5 mg per day).

Do not exceed the recommended dosage!

If there is no improvement in your condition within 5 days, you should contact your doctor.

Attention: Do not swallow! This drug is intended for external use only.

Usage:

First, wash your hands thoroughly. Remove the suppository from the packet. Lie on your side and insert the suppository deep inside the anus with the help of a finger.

Note! If the suppository is too soft, it can be hardened in the refrigerator for about half an hour or under cold running water before removing it from the package. Wash your hands after the insertion of the suppository.

Contalax usually produces evacuation of the bowel within 60-95 minutes.

If you have taken an overdose: or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.



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How can you contribute to the success of the treatment:

You should make certain to drink liquids during the day that will help soften the stool.

Do not take medicines in the dark! Check the label and dose each time you take your medicine. Wear your glasses if you need them. If you have other questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects:

Like all medicines, the use of Contalax may cause some effects in some patients. Do not be alarmed while reading the list of side effects; you may not suffer from any of them.

Discontinue treatment and consult your doctor immediately

if: In rare cases of acute allergic reaction that might cause swelling of the face or the throat, breathing difficulties or dizziness.

In rare cases of uncustomed tiredness or debility, a faster heart rate and confusion should indicate an electrolyte imbalance.

Additional side effects:

Common side effects:

(appear in 1-10 of 100 patients): abdominal pain or stomach cramps, diarrhea and nausea.

Uncommon side effects:

(appear in 1-10 of 1,000 patients): Blood in the stool, vomiting, abdominal discomfort and inside and around the anus or dizziness.

Rare side effects:

(appear in 1-10 of 10,000 patients): Colitis - an inflammation of the colon, characterized by abdominal pain and diarrhea.

Dehydration. Allergic reaction that might cause facial rash.

Fainting.

Side effects of unknown frequency:

This medicine might cause a color change in stool or urine.

There is no need for concern because of the color change.

If you feel a side effect or if one of the side effects worsens or

If you experience side effects that are not listed in this leaflet, you must consult your doctor.

You may report side effects to the Ministry of Health (www.health.gov.il) by clicking the link "Adverse drug reactions report" that you will find in the MoH homepage,

or by the URL:

<https://forms.gov.il/forms/Resources/DownloadSetup/AGFormsDownloadToolbar.htm?formid=AdversEffectMedic@moh.gov.il>

If you feel a change in your general health, consult your doctor immediately.

5. How to store the medicine?

* **Avoid Poisoning!** This medicine and all other medicine must be stored in a safe place out of the reach of children and/or infants in order to avoid poisoning.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor.

* Do not use the medicine after the expiry date (exp. date) stated on the package.

The expiry date refers to the last day of that month.

* Do not store in a temperature exceeding 25°C.

* Store in the original package.

6. Additional information

Besides the active ingredients, the medicine contains also: Hardened fat, Methylparaben.

How does the medicine look like and what are the contents of the package? White to pale yellow colored torpedo shaped suppositories, 25 suppositories, each containing 10 mg active ingredient.

Registration owner: Fischer Pharmaceutica Labs (1975) Ltd. POB 39071, Tel Aviv 61390.

Manufacturer's name and address: Ben-Shimon Floris Ltd, Misgav Industrial Park, MOP Misgav, 20174

The Ministry of Health has reviewed and approved the content of this leaflet on the 17.10.2017.

The medicine's licence number in the state medicine registry at the Ministry of Health is 118.13.23519.