PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Laxadin®

Film-coated Tablets

The active ingredient and its quantity:
Each film-coated tablet contains:
Bisacodyl 5 mg
For information on inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to relieve constipation in adults and children over 6 years of age, in ambulatory patients or in bedridden patients, and is also given as preparation before certain tests.

Therapeutic group:
A laxative that contains an agent that promotes stimulation of the large intestine (contact laxative).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to bisacodyl or to any of the other ingredients of the medicine (see section 6 – "Further Information")
- You have an intolerance (sensitivity) to certain sugars or cannot digest certain sugars (as the tablet contains a small amount of lactose)
- You suffer from severe dehydration
- You have a bowel problem called "ileus" (blockage in the intestine)
- You have a serious abdominal problem, such as appendicitis
- You have severe abdominal pain accompanied by nausea and vomiting
- You have an intestinal obstruction or chronic intestinal dysfunction
- You have inflammation of the bowel (small or large intestine)

Special warnings regarding use of the medicine
Prolonged use may lead to dependence on laxatives (such as this one), and diarrhea. Do not use this medicine frequently or for a prolonged period without consulting a doctor.
This medicine is only intended for constipation that persists for a few days, since long-term use of the medicine may cause the bowel to depend on laxatives in order to generate a bowel movement. Inactivity of the bowel for a day or two does not justify use of this medicine.
Do not use Laxadin for other purposes such as "body cleansing" and the like.

Is the medicine effective for weight loss?
Laxatives (including bisacodyl) are not effective for weight loss. They do not reduce the absorption of calories or food. They can cause watery stools (diarrhea), abdominal pains and dehydration. Dehydration can erroneously be considered weight loss.
Overuse of laxatives may damage your health in the following ways:
- Causing disturbances in the balance of electrolytes and minerals. Sodium, potassium, magnesium, and phosphorus are electrolytes and minerals that are required in very specific concentrations for the proper functioning of the nerves and muscles, including the muscles of the colon and heart. Disruption of this delicate balance can cause impaired functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.
- Avoid overuse of laxatives so as not to impair intestinal function.

Before treatment with Laxadin, tell the doctor if:
- You are suffering, or have suffered in the past, from rectal bleeding.
- You are suffering from strong abdominal pain.

Children and adolescents
The medicine is not intended for use in children under 6 years of age.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- Diuretics, e.g., bendrofluazide or furosemide
- Steroids, e.g., prednisolone
- Other laxatives
- Do not take medicines to reduce stomach acid (from the proton pump inhibitor group) or antacids, within an hour before or after taking this medicine.

Wait at least two hours between taking this medicine and taking other oral medicines, as Laxadin may affect the absorption of the medicines.

Use of the medicine and food
Do not consume milk within one hour before or after taking Laxadin tablets, since it will inhibit the normal activity of Laxadin tablets.

Pregnancy, breastfeeding and fertility
If you are pregnant, are planning to become pregnant, or are breastfeeding, consult a doctor before taking Laxadin.

Driving and using machinery
Some patients may feel dizzy or faint while taking this medicine. If you experience these effects, wait until they pass before driving or using machinery.

Important information about some of the ingredients of the medicine
Laxadin contains lactose monohydrate. If you have been told by the doctor that you have an intolerance (sensitivity) to certain sugars, consult the attending doctor before taking the medicine.
Each tablet contains 40 mg lactose monohydrate.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the preparation dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:
Dosage for adults: 1-3 tablets in the evening, before bedtime.
If this is the first time you are taking the medicine, start with one tablet and increase the dosage as necessary.
Do not take more than 3 tablets per day.
Dosage for children over 6 years of age: One tablet in the evening, before bedtime.
Do not exceed the recommended dose.

Duration of treatment
As with other laxatives, do not take Laxadin for more than 5 consecutive days.
If you need to take laxatives every day, refer to a doctor to find the cause of the constipation. Overuse can be harmful.

Instructions for use of the medicine
- Swallow the tablet whole with water.
- Do not take milk, antacids or proton pump inhibitors (medicines to reduce gastric acid) within one hour before or after taking Laxadin tablets. This is because they will inhibit the normal activity of Laxadin tablets.
- Swallow the medicine in the evening, before bedtime.
- Do not chew or crush, and do not halve the tablet so as not to impair the activity of the coating of the tablet.
- Be sure to drink fluids during the day to help soften the stool and prevent dehydration.
  The preparation induces intestinal activity usually within 6-12 hours, but sometimes more time is necessary (up to 24 hours).

If you accidentally take a higher dosage
If you take too many Laxadin tablets or you took Laxadin tablets for a prolonged period of time, damage may be caused and the following symptoms may occur:
- Imbalance of fluid and salts in the body, which may affect muscle tonus (such as the bowel muscles), and salts in the blood.
- Low levels of potassium in the blood (called hypokalemia), which may cause a feeling of tiredness or dizziness, muscle weakness and uneven heart-beat.
- Dehydration, which may manifest by feeling thirsty, feeling faint, headaches and passing little urine.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
Adhere to the treatment regimen as recommended by the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Laxadin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue treatment and refer to a doctor immediately if you experience any of the following side effects:
A severe and rare allergic reaction, including swelling of the face, throat, and breathing difficulties or dizziness.

Common side effects (effects that occur in less than 1 user in 10):
- Abdominal cramps or pain
- Diarrhea
- Nausea

Uncommon side effects (effects that occur in less than 1 user in 100):
- Blood in the stool
- Vomiting
- Abdominal discomfort
- Discomfort inside and around the anus
- Dizziness
- This medicine may cause a change in the color of the urine. Such a change is no cause for concern.

Rare side effects (effects that occur in less than 1 user in 1,000):
- Colitis (inflammation of the large intestine causing abdominal pain and diarrhea)
- Dehydration
- Allergic reaction that may cause a skin rash
- Fainting

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- Do not dispose of medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, methacrylic acid copolymer dispersion, talc, esma spreng, starch, gelatin, povidone, magnesium stearate, triethyl citrate, polyethylene glycol 4000, simethicone, methyl cellulose 400, sorbic acid.

What the medicine looks like and the contents of the package
White, round, biconvex film-coated tablet.
The package contains: 10, 20, 30, 50 or 1,000 tablets. Not all package sizes may be marketed.

Name of Manufacturer and License Holder and Address
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020
This leaflet was revised in December 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
018.16.24419