Patient package insert according to Pharmacists' Regulations (Preparations), 1986

This medicine can be sold with a physician's prescription only

BEKUNIS, DRAGEES

Each dragee contains:
150-220 mg dry extract of Tinnevelly Senna pods corresponding to 20 mg hydroxyanthracene derivatives calculated as Sennoside B.

For list of inactive ingredients, please see section 6.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your physician or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their condition is similar to yours.

This medicine is intended for adults, children and adolescents above 12 years of age.

1. What is the medicine intended for?

- For short-term relief of constipation.

Therapeutic group: Contact laxative

2. Before using the medicine:

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient (Senna plant) or to any of the other ingredients of this medicine (see section 6).
- you suffer from chronic intestinal inflammations (e.g. Crohn's disease, ulcerative colitis),
- intestinal obstruction or appendicitis (symptoms such as: abdominal pain, cramps or bloating, nausea and vomiting of unknown causes).
- you suffer from abdominal pain of unknown cause or in states of dehydration.
- The patient is under 12 years of age.

Special warnings regarding the use of this medicine:

- **Before taking Bekunis tell your physician if:**
  - You are sensitive to any type of food or medicine.
  - You suffer from impaired heart function or from rectal bleeding.
- Prolonged use may cause dependency upon laxatives such as this one and diarrhea.
- Do not use **Bekunis** Dragees frequently or for a prolonged period without consulting your physician.
- **Bekunis** Dragees are intended only for constipation that lasts a few days and does not respond to a change in diet or to a preparation that expands the volume of feces. Missing a bowel movement for a day or two does not justify its use. Furthermore, do not use this medicine for other purposes such as "body cleansing" etc.
- If, after taking this medicine, you still do not have a bowel movement, stop treatment and refer to your physician.
- Patients suffering from incontinence should avoid prolonged skin contact with the feces while taking this medicine by frequent changing of pads.

If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, tell your physician or pharmacist.
Especially if you are taking:

- Other laxatives, corticosteroids, liquorice.
- Medicines for heart diseases (e.g. glycosides such as digoxin, antiarrhythmic medicines), diuretics.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding consult your physician or pharmacist before using the medicine.

Important information about some of the ingredients of this medicine:
These dragees contain lactose, glucose and sucrose. If you have been told by a physician in the past that you are intolerant to certain sugars, consult a physician before starting treatment with this medicine.

3. How to use this medicine

Always use according to your physician's instructions. Check with your physician or pharmacist if you are not sure.

The dosage and administration will be determined by the physician only.
Usual recommended dosage is:
One dragee of **Bekunis** before bedtime.

Do not exceed the recommended dose.
This medicine is not intended for children under 12 years of age.

Be sure to drink fluids during the day to help soften the feces. This medicine induces bowel movements after approximately 8-12 hours.

Attention: you must wait at least two hours between taking **Bekunis** Dragees and another medicine to be taken orally.

- Do not crush or divide the dragee, since the medicine has a protective coating.
- Swallow the dragee whole with plenty of fluids.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by your physician.

If you forget to take this medicine at the specified time, do not take a double dose. Take the next dose at the regular time and consult your physician.

- Do not take medicines in the dark. Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your physician of pharmacist.

4. Side effects:

Like any medicine, **Bekunis** can cause side effects in some of the users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop use of this medicine and refer to your physician immediately if the following appears:

- Abdominal cramps, hypersensitivity (itching, urticaria, local or generalized rash) (very rare).
- Severe side effects of the digestive system which may be caused by chronic use or overdose: painful abdominal cramps, diarrhea, signs of loss of fluids and electrolytes (confusion, heart function disturbances, tiredness or muscle weakness and/or cramps), especially in concomitant use with cardiac medicines (glycosides such as digoxin), diuretics and adrenal steroids.

Additional side effects:
Redness of the urine color, this change is not a cause for concern.
Chronic use may lead to the presence of protein and blood in the urine, as well as pigmentation of the intestine (pseudomelanosis coli), a non-harmful effect which generally disappears after you stop using the medicine.

If a side effect appears, if any of the side effects worsens or if you experience a side effect not specified in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting, or via the following link:
https://forms.gov.il/globaldata getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician!
- 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.
- Store at a temperature below 30°C.
- This medicine may be used up to 6 months after the first opening of the package.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Sucrose, Talc, Cellulose Microcrystalline, Lactose Anhydrous, Eudragit L 30 D, Calcium Carbonate, Silicon Dioxide Methylated, Titanium Dioxide (E 171), Gelatine, Magnesium Stearate, Gum Arabic spray dried, Liquid Glucose (Dry Substance), Macrogol 6000, Polysorbate 80, Stearic Palmitic Acid, Montan Glycol Wax, Carboxymehtylcellulose Sodium.

What the medicine looks like and contents of the pack: each package contains a bottle with 45 slightly shiny gray – white dragees.

Manufacturer and is address:
Roha, Arzneimittel GmbH, Bremen, Germany.

This leaflet was checked and approved by the Ministry of Health in July 2017.

Drug registration number at the national medicines registry of the Ministry of Health:
036 62 25740 00

Bekunis PIL PB1017-04

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