

MIDRO Tea

Tea 75%

Active ingredients:

Each 100 g contains: Sennae Folium 75 g

75% Folium Sennae equivalent to 2.7% hydroxyanthracenes

Inactive ingredients and allergens: see section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

The medicine is not intended for children under the age of 12 years.

1. What is this medicine intended for?

This medicine is indicated for the treatment of constipation.

Therapeutic group: Laxative.

2. Before using this medicine

X Do not use this medicine if:

- You are sensitive to any of the ingredients that this medicine contains
- In the case of intestinal occlusion
- In the case of chronic intestinal dysfunction
- In the case of acute intestinal inflammation such as Crohn's disease or ulcerative colitis
- In the case of intestinal bleeding
- In the case of gastrointestinal tract obstruction
- In the case of symptoms of appendicitis
- In the case of abdominal pain of unknown reason
- In the case of severe dehydration associated with loss of fluids and electrolytes
- Children under 12 years

I Special warnings regarding the use of this medicine

- Prolonged use may cause diarrhea and dependence on laxative preparations of this type.
- Do not use this medicine frequently, or for a long period exceeding 1-2 weeks, without consulting a physician.
- If you are sensitive to any type of food or medicine, inform your physician before commencing treatment with this medicine.
- This preparation is indicated only for constipation continuing for several days. A lack of bowel movement for 1-2 days does not justify use of this medicine.
- Upon chronic use, abuse or use at dosages higher than the recommended dosages, you may develop diarrhea with fluid loss and electrolyte imbalance (including potassium loss); dependence associated with the need to increase the dosage, paralytic ileus with functional intestinal obstruction.
- Do not use this preparation for other purposes, such as "body cleansing" etc.

Before using "Midro Tea", tell your physician if:

- You are pregnant or breast-feeding.
- You suffer or have previously suffered from impaired cardiac function.
- You have rectal bleeding.
- You have intense abdominal pain.
- You have signs of appendicitis (such as: abdominal pain, nausea and vomiting).

If you are taking or have recently taken other medicines, including nonprescription medicines and nutritional supplements, inform your physician or pharmacist. In particular if you are taking:

- Other laxatives
- Antacids
- Diuretics
- Licorice based medicines
- Corticosteroids
- Medicines for the treatment of heart failure (such as Digoxin)
- Antiarrhythmic medicines
- Antihistamines (such as Terfenadine)

Allow a lapse of at least two hours between taking this medicine and taking another oral medicine.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding you should consult a physician or pharmacist before using this medicine.

Driving and using machines

Midro Tea is not expected to affect the ability to drive or to operate machines. However, if you experience dizziness, you must be careful while driving and operating machines.

3. How should you use the medicine?

You should check with the physician or the pharmacist if you are unsure.

This medicine is not intended for children under the age of 12 years.

The dosage and treatment will be determined only by the physician. The usual acceptable dosage is:

Unless instructed otherwise by the physician, chew 1/4 up to 1½ full measuring scoops (maximum 1.5 gram). Chew or swallow the medicine with some water about 1 hour before bedtime.

Start with 1/2 full measuring scoop of Midro Tea.

Adjust the dose according to your needs by increasing or reducing it as required. Do not exceed the daily dose of 1½ full measuring scoops.

If there is no improvement in your condition within 1 week, refer to your physician.

Do not exceed the recommended dose.

Persist with the treatment as recommended by the physician.

Allow a lapse of at least two hours between taking this medicine and taking other oral medicines.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

How can you contribute to the success of the treatment?

Make sure your liquid intake is sufficient in order to help soften the stool. This preparation causes a bowel movement usually within 6-12 hours, but occasionally more time is needed (up to 24 hours).

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 the physician or the pharmacist.

4. Side effects

Like all medicines, Midro Tea may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

- Rash
- Abdominal spasms
- Diarrhea

Rare side effects (<1/10,000)

- Unusual weakness or fatigue
- Increased heart rate
- Confusion
- Abdominal flatulence
- Abdominal pain

These effects may be signs of electrolyte loss. Upon occurrence of any of these side effects, stop the treatment and contact your physician immediately.

This medicine may cause a change in the colour of the urine. Such a change should not be a cause for worry.

If any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, or if there is a change in your general health, **you should consult the physician immediately.**

Reporting side effects:

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the 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 medicine should be kept in a close place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature above 25°C.
- Avoid exposure to light.
- After first opening, use the medicine for up to 1 year of the day of opening, but never use it after the expiration date indicated on the package.
- Store in the original package.

6. Additional information

- In addition to the active ingredient the medicine also contains:
Fructus Carvi, Radix Liquiritiae, Folium Menthae Piperitae, Malvae Flower, Calcatrippae Flower.
 - What does the medicine look like and what are the contents of the package:
Midro Tea product is a herbal mixture of heterogeneous green color with purple flakes, of mild aromatic odor. The mixture is packed in a paper bag stored in a carton box.
The product package contains 80 grams.
- Registration holder: Neopharm (ISRAEL) 1996 Ltd., POB 7063, Petach-Tikva 49170.
- Manufacturer: Midro AG, Switzerland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 130-27-20919-00.
- This leaflet was checked and approved by the Ministry of Health in: 03/2016.