

**PATIENT LEAFLET IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Notensyl tablets 10 mg

Each tablet contains 10 mg Dicyclomine Hydrochloride

For inactive ingredients and allergens in the preparation – see the section “Important information about some of the ingredients of the medicine” and section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. 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 2 years old.

1. What is the medicine intended for?

The medicine is intended as an aid in treatment of Irritable Bowel Syndrome.

Therapeutic class: The active ingredient belongs to the class of anticholinergic agents.

2. Before using the medicine:

❗ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (dicyclomine) or any of the other ingredients this medicine contains (see section 6). Signs of an allergic reaction include: rash, difficulty swallowing or breathing, swelling of the lips, face, throat or tongue.

Special warnings regarding the use of the medicine

❗ Before treatment with Notensyl tablets, tell the doctor if you:

- Suffer from glaucoma. Signs include eye pain accompanied by blurred vision.
- Suffer from an enlarged prostate.
- Suffer from indigestion or heartburn caused by a hiatus hernia.

❗ Tests and follow-up:

The preparation may impair the results of an acid secretion test in the stomach.

❗ Drug-drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

Notensyl should be taken separately from other medicines, because Notensyl may affect the way other medicines work, or alternatively, other medicines may affect the way Notensyl works.

❗ Use of the medicine and food

The medicine should be taken after or before the meal.

❗ Pregnancy, breastfeeding and fertility

If you are pregnant, think you may be pregnant, are planning to become pregnant, are breastfeeding or are planning to breastfeed, consult your doctor before starting treatment.

❗ Driving and operating machinery

You may experience dizziness, tiredness, sleepiness, or blurred vision during treatment. In such cases, do not drive or operate heavy machinery. Children should be cautioned against riding a bicycle or playing near a road etc.

❗ Important information about some of the ingredients of the medicine

The medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

Each tablet contains 1.05 mg of sorbitol.

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 about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is:

For adults and children over 12 years old:

1-2 tablets, 3 times a day.

Children over 2 years old: one tablet, 3 times a day.

Do not exceed the recommended dose.

The tablet should be swallowed with some water. Do not chew. If necessary, the tablet may be crushed.

If you accidentally took a higher dosage the following effects may occur: headache, dizziness, nausea, dry mouth or difficulty swallowing, blurred vision and dry and warm skin.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If you stop, your cramps and pain may come back.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Notensyl may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using the medicine and contact a doctor or go to a hospital immediately if you experience:

- An allergic reaction. The signs may include: rash, difficulty swallowing or breathing, swelling of the lips, face, throat or tongue.

Additional side effects:

- Dry mouth, thirst
- Dizziness
- Tiredness, drowsiness
- Blurred vision
- Rash
- Loss of appetite (anorexia)
- Nausea, vomiting
- Constipation
- Headache
- Pain or difficulty in urination

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

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp.) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C.

6. Additional information:

In addition to the active ingredients the medicine also contains:

Lactose, Maize Starch, Povidone, Magnesium Stearate, Sorbitol Solution 70%.

What does the medicine look like and what are the contents of the package:

Biconvex, white tablets.

The tablets are supplied in a carton package containing 20 tablets in a blister pack.

Manufacturer/marketing authorization holder and address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi 83057.

This leaflet was revised in May 2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1178523254

