

**PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

Tarodex Pediatric syrup **Tarodex Adult syrup**

Composition:

Each 5 ml contains:

Dextromethorphan
hydrobromide 7.5 mg

For the list of inactive ingredients and allergens in the preparation - see section 6 "Further Information".

Composition:

Each 5 ml contains:

Dextromethorphan
hydrobromide 15 mg

Read this 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.

The medicine is not intended for infants under the age of 1 year.

In children 1-6 years of age, use requires a doctor's prescription.

Refer to the doctor if the signs of the disease (symptoms) worsen or do not improve within 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the relief of cough.

Therapeutic group

From the opiates group.

2. BEFORE USING THE MEDICINE

❑ Do not use the medicine:

- in infants under the age of 1 year.
- if you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine. For the list of inactive ingredients – see section 6 "Further Information".
- in case of persistent cough or chronic cough due to smoking, asthma or emphysema or cough accompanied by excessive phlegm.

Special warnings regarding use of the medicine

❑ Before treatment with Tarodex, inform the doctor if:

- you are pregnant or breastfeeding.
- you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma), the liver.
- you suffer from a high fever, persistent headache or dizziness.
- you are sensitive to any food or medicine.

Additional warnings:

- Do not use frequently or for a prolonged period without consulting the doctor.

❑ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

- medicines affecting the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's, for epilepsy) – their suppressive effect on the central nervous system may be increased.
- Monoamine oxidase inhibitors (MAOI) – due to increased risk of serotonin syndrome (which is manifested by, among other things, high fever, high blood pressure, heart rate disturbance).

❑ Pregnancy and breastfeeding

Consult a doctor before using the medicine if you are pregnant or breastfeeding.

❑ Driving and use of machines

There is no known effect on driving and use of machines.

❑ Important information regarding some of the ingredients of the medicine

Tarodex Pediatric Syrup:

Each 5 ml contains 1.67 mg sodium.

Each 5 ml contains 76 mg saccharin.

Tarodex Adult Syrup:

Each 5 ml contains 2.25 mg sodium.

Each 5 ml contains 190 mg saccharin.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally:

For children 1-6 years of age, use requires a doctor's prescription.

Pediatric syrup:

Age 2-6 years: 5 ml every 6-8 hours. Do not exceed 20 ml in 24 hours.

Age 6-12 years: 10 ml every 6-8 hours. Do not exceed 40 ml in 24 hours.

Adult syrup:

5 ml every 4 hours or 10 ml every 6 hours.

Do not use this medicine in children below the age of 1 year.

Do not exceed the recommended dose.

If there is no improvement in your condition within 7 days, refer to the doctor.

Be sure to measure the dose in the provided dedicated measuring cup.

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

If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

In children 1-6 years of age – adhere to the treatment regimen 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 Tarodex Syrup 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.

Discontinue use and refer to a doctor immediately in the event of:

Dizziness, drowsiness, nausea, vomiting, stomach pain (rare).

Side effects and drug interactions in children and infants:

Parents must inform the attending doctor of any side effects, as well as any additional medicine being given to the child!

See above for details of special side effects and drug interactions.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

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 of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from 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.

- At a temperature below 25°C.
- Store in the original package.
- After opening, use within 3 months.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Tarodex Pediatric Syrup

Lycasin, Glycerin, Citric acid, Sodium citrate, Sodium benzoate, Saccharin sodium, Cherry flavour, FD&C Red #40, Purified water.

Each 5 ml contains 1.67 mg sodium.

Each 5 ml contains 76 mg saccharin.

Tarodex Adult Syrup

Lycasin, Glycerin, Saccharin sodium, Vanillin, Citric acid, Sodium benzoate, Raspberry flavour, Sodium citrate, Peppermint flavour, FD&C Red #40, D&C Yellow #10, Purified water.

Each 5 ml contains 2.25 mg sodium.

Each 5 ml contains 190 mg saccharin.

What the medicine looks like and the contents of the package:

Tarodex Pediatric Syrup – A clear, light red, cherry scented syrup, packaged in a plastic bottle with a child-proof safety cap. Each bottle contains 120 ml.

Tarodex Adult Syrup - A clear, orange-red, raspberry-mint scented syrup, packaged in a plastic bottle with a child-proof safety cap. Each bottle contains 120 ml or 30 ml. Not all package sizes are marketed.

Manufacturer and license holder

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., P.O.B. 10347 Haifa Bay 2624761.

This leaflet was checked and approved by the Ministry of Health in November 2013.

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

Tarodex Pediatric Syrup: 6209.27831

Tarodex Adult Syrup: 6210.27830