Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Oxacatin®
Syrup

Active ingredients

Each 5 ml contain:
oxomemazine 1.65 mg
potassium guaiacol sulphonate 33.30 mg

Inactive ingredients and allergens in this medicine: see section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or 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 to yours.

1. What is this medicine intended for?

Antitussive syrup, expectorant.

Therapeutic group:
Oxomemazine - cough suppressant antihistamine of the phenothiazine group.
Potassium guaiacol sulphonate – expectorant.

2. Before using this medicine:

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredients (oxomemazine or potassium guaiacol sulphonate) or to any of the other ingredients in this medicine (see section 6).
- If you are allergic to an antihistaminic medicine used to treat allergies.
- In children under 2 years of age.
- If you have ever had a significant decrease in the level of certain white blood cells (granulocytes) in the blood (agranulocytosis).
- If you experience difficulty urinating (prostate problem or other problems).
- If you are at risk of angle-closure glaucoma (high intraocular pressure that may impair eyesight).
- If you are taking a medicine containing cabergoline or quinagolide (used to inhibit excessive prolactin production) (see section "Drug interactions").

Special warnings about using this medicine:

- If the cough persists despite using Oxacatin syrup, do not increase the dosages. Consult your doctor. Cough is actually a symptom which may be triggered by various causes: respiratory infections, bronchitis, influenza, allergy, asthma, pertussis, irritation, etc.
- Avoid exposure to sunlight or ultraviolet rays (UVA) during treatment.
- Use the medicine with caution due to the risk of drowsiness.
  Combination with other sedatives is not recommended (see section "Drug interactions").

Before treatment with Oxacatin, tell your doctor if:

- You have a chronic bronchial or pulmonary disease with cough and mucus.
- You have a chronic liver disease (severe liver failure) or chronic kidney disease (severe kidney failure), your doctor will have to adjust the dosage for your condition.
- You have a cardiovascular disease.
- You have epilepsy.
- You are over 65 years of age (especially in case of chronic constipation, difficulty urinating due to increased prostate volume, hypotension, dizziness or drowsiness).
- Your child suffers from asthma or gastroesophageal reflux.

During treatment, consult your doctor:
If you have fever with or without infection signs (such as sore throat), pallor or sweating.
In case of doubt, do not hesitate to contact your doctor or pharmacist for consultation.

Smoking
Use of tobacco exacerbates cough or causes prolonged cough.

Children and adolescents
Do not use the medicine in children below the age of 2 years.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Never take Oxacatin syrup with medicines containing cabergoline or quinagolide (used to inhibit excessive prolactin production (see section “Do not use this medicine")).
Avoid taking medicines containing alcohol during the treatment period.
Wait at least 2 hours between taking Oxacatin syrup and taking cytoprotectants, antacids or charcoal (used to relieve digestive disorders).
Many other medicines can decrease alertness and cause drowsiness. Combining them with Oxacatin may increase this effect. Tell your doctor or pharmacist if you are taking:
- morphine derivatives (used to control pain, to suppress cough or for drug addiction withdrawal)
- neuroleptic medicines
- benzodiazepines (medicines for treatment of anxiety)
- barbiturates
- hypnotic medicines (sleeping pills)
- antidepressants
- sedating antihistamines (sedatives)
- certain antihypertensive medicines
- medicines containing baclofen and thalidomide
- mefloquine, chloroquine, bupropion, tramadol.

Using this medicine and food
Take the medicine with a meal or with milk.

Using this medicine and alcohol consumption
Avoid drinking alcohol or taking a medicine containing alcohol during treatment.

Pregnancy and breastfeeding
Pregnancy
Usually, this medicine should not be used during the first trimester of pregnancy, unless advised otherwise by your doctor.
If you find out that you are pregnant during the treatment, consult your doctor immediately: only your doctor will be able to adjust the treatment to your condition.
At the end of pregnancy, misuse of this medicine may cause harmful effects on the newborn. Therefore, you should always ask your doctor for advice before using it and never

exceed the recommended dose and duration of treatment.

Breastfeeding
This medicine passes into breast milk. In view of the pronounced sedative properties of the medicine, avoid taking it if you are breastfeeding.
If you are pregnant or breastfeeding, if you think you are pregnant or are planning a pregnancy, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
This medicine may cause drowsiness, especially at the beginning of treatment. It is not advisable to drive or use machines if you experience this effect. The risk of drowsiness is increased if you consume alcoholic drinks, medicines containing alcohol or other sedating medicines (see section “Drug interactions").

Important information about some of this medicine’s ingredients
This medicine contains sugar. If you have been told by your doctor that you have intolerance to certain sugars, contact your doctor before taking this medicine. It may also cause damage to teeth.
This medicine contains sorbitol. Each 5 ml contain 250 mg sorbitol, equivalent to the concentration of 5% w/v. Sorbitol is a source of fructose. If you have been told by your doctor that you or your child have intolerance to certain sugars, or if you have been diagnosed with hereditary fructose intolerance, a rare genetic disorder, contact your doctor before you or your child take this medicine.
This medicine contains sodium benzoate. Each 5 ml contain 33.3 mg sodium benzoate, equivalent to the concentration of 0.7% w/v. This medicine contains less than 1 mmol (23 mg) sodium per a 5 ml dose, therefore it is essentially "sodium free".
This medicine contains propylene glycol. Each 5 ml contain 250 mg propylene glycol, equivalent to the concentration of 5% w/v. If your child is younger than 5 years of age, talk to your doctor/pharmacist before administering this medicine, especially if your child is using medicines containing propylene glycol or alcohol. If you are pregnant or breastfeeding, if you have a liver or kidney disease, do not take this medicine, unless recommended by your doctor. Your doctor may conduct additional tests while you are taking this medicine.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Use the enclosed measuring cup. Do not use a home teaspoon to measure the medicine quantity. Home teaspoons vary in size, and you may not receive the correct quantity of the medicine.

Only your doctor will determine your dose and how you should take this medicine.

It is advisable to take Oxacatin syrup in the evening due to the sedating effect of the medicine, especially at the beginning of treatment.

Do not exceed the recommended dose.

Method of administration
This medicine should be taken by mouth. Use the measuring cup provided in the box.
Do not hold the medicine in the mouth beyond the time required to swallow it.

Treatment duration
The treatment should be short (a few days) and used only when cough occurs.
If the cough persists, ask your doctor for advice.

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

Taking an overdose of Oxacatin syrup may cause seizures (especially in children), drowsiness, alertness problems, coma.

If you forgot to take the medicine
Do not take a double dose to compensate for the single forgotten dose.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Oxacatin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using the medicine and contact your doctor immediately if:

- You develop signs of allergy to the medicine such as:
  - redness of the skin, eczema, purple spots on the skin (purpura)
  - hives
  - edema, sudden swelling of the face and/or neck, which may cause difficulties breathing and may be dangerous (Quincke's edema)
  - sudden collapse with a severe drop in blood pressure (anaphylactic shock)
- You have an exaggerated skin reaction after exposure to sun or UV radiation
- You have a decrease in the number of certain blood cells: white cells (neutropenia, agranulocytosis), platelets (thrombocytopenia) or red cells (hemolytic anemia)

Additional side effects

- drowsiness, decreased alertness, especially at the beginning of treatment
- memory or concentration problems, dizziness
- difficulty coordinating movements, tremor
- confusion, hallucinations
- dry mouth, visual disturbances, difficulty urinating (urinary retention), constipation, palpitations, severe drop in blood pressure when standing up, sometimes resulting in dizziness and/or fainting (orthostatic hypotension).

More rarely, signs of excitation (restlessness, nervousness, insomnia) can occur.

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- Eosinophilia, which is an increase in the number of eosinophils (a type of white blood cell) diagnosed in a blood test.
- Thrombocytopenia, which is a decrease in the number of platelets (blood cells which help with blood clotting), that is diagnosed in a blood test and may cause bleeding and bruising (thrombocytopenic purpura).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25˚C.
- Shelf life after opening the medicine: 12 months.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Sugar, sorbitol 70% solution, propylene glycol, sodium benzoate, sodium citrate, caramel flavor, citric acid anhydrous, caramel color liquid, purified water.

What the medicine looks like and contents of the pack:

A clear solution with caramel odor.
The syrup is packed in a plastic bottle with a child-resistant cap. Each pack contains 30 ml or 120 ml and a measuring cup.
Not all pack sizes may be marketed.

Manufacturer's and Registration Holder's name and address: Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay, 2624761.

Revised in September 2023 according to MOH guidelines.

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

030-54-21959-00