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

This medicine is dispensed with a doctor's prescription only

URAMOX®
Tablets

Active ingredient
Each tablet contains 250 mg acetazolamide

For a list of inactive ingredients and allergens in this medicine, see section 2 under '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 to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

- As a supplementary treatment of edema that is due to heart failure or is caused by medication.
- As a supplementary treatment of different types of glaucoma.
- To relieve and prevent acute mountain sickness.

Therapeutic group: carbonic anhydrase inhibitor.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to sulphonamides, sulphonamide derivatives including acetazolamide or to any of the other ingredients in this medicine (listed in section 6).
- you have severe liver problems.
- you have or have ever had severe kidney problems.
- you have a particular type of glaucoma known as chronic non-congestive angle-closure glaucoma (your doctor will be able to advise you).
- you have reduced function of the adrenal glands - glands above the kidneys (also known as Addison's disease).
- you have low blood levels of sodium and/or potassium or high blood levels of chlorine (your doctor will advise you).
- you are pregnant.

Special warnings about using this medicine

- **Before starting treatment with Uramox, tell your doctor if:**
  - you have, or have ever had, kidney problems, such as kidney stones.
  - you have lung problems, such as chronic bronchitis or emphysema, which cause difficulty in breathing.
  - you are over the age of 65.
  - a small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves; if at any time you have these thoughts, immediately contact your doctor.

- This medicine may affect certain medical tests. If you undergo any medical tests, tell the doctor that you are taking Uramox.
- A decrease in vision or eye pain could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion or choroidal detachment). This can happen within hours of taking Uramox. Talk to your doctor promptly if you experience these symptoms.

Other medicines and Uramox
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines for the heart, such as cardiac glycosides (such as digoxin)
- medicines to reduce blood pressure
- medicines to thin the blood (such as warfarin)
- medicines to lower sugar in the blood (such as: metformin, gliclazide)
- medicines for epilepsy or fits (mainly phenytoin, primidone, carbamazepine or topiramate)
- medicines that affect the metabolism of folic acid, such as: methotrexate, pyrimethamine, or trimethoprim
- steroids such as prednisolone
- aspirin and similar medicines, such as salicylic acid or choline salicylate for mouth ulcers
- other medicines in the group of medicines called carbonic anhydrase inhibitors (such as dorzolamide or brinzolamide which are also used to treat glaucoma)
- amphetamines (stimulants), quinidine (treats an irregular heartbeat), methenamine (prevents urinary tract infections) or lithium (treats severe mental problems)
- sodium bicarbonate therapy (used to treat high levels of acid in the body)
- ciclosporin (used to suppress the immune system)

Using this medicine and food
Swallow the medicine with water. Take this medicine with or immediately after a meal*.*

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

Pregnancy
Do not take the medicine if you are pregnant, think you are pregnant or are planning to have a baby.

Breastfeeding
If you are breastfeeding, you may take this medicine only after consulting your doctor.

Driving and using machines
If the medicine makes you feel drowsy or confused, do not drive or operate machines. The medicine may occasionally cause short-sightedness. If this happens and you feel that you can no longer drive safely, you should stop driving and contact your doctor.

Important information about some of this medicine's ingredients
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking the medicine.
This medicine contains less than 1 millimole (23 mg) sodium per tablet, so it is essentially 'sodium free'.

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.
The dosage varies from person to person, depending on their condition.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

Glaucoma**:**
Adults: 250-1,000 mg (1-4 tablets) a day, in divided doses.

Edema:
Adults: Starting dose is 250-375 mg (1-1.5 tablets) once a day in the morning. Your doctor will adjust the dose and tell you how often to take your dose.

Mountain sickness:

2-4 tablets a day, in divided doses.
In case of rapid ascent (such as in rescue operations), the recommended dosage is 4 tablets a day.
It is preferable to begin treatment 24-48 hours before ascent and continue for 48 hours while at high altitudes or for as long as necessary to relieve symptoms.

Do not chew! The tablet can be split or crushed if necessary.

Do not exceed the recommended dose.

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**.**

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember. However, if the next dose is due in two hours or less, skip the forgotten dose and continue taking the tablets at the usual times. Never take two doses together to make up for a 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 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

As with any medicine, using Uramox may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

- **All medicines can cause allergic reactions, although serious allergic reactions are very rare. If you experience sudden wheezing, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting the whole body), consult a doctor immediately.**

- Uramox may affect the cells in your blood so you may be at a higher risk of infections and your blood may not clot properly. If you have a sore throat or fever or you notice bruises or tiny red or purple spots on your skin, **consult your doctor immediately**. If your muscles feel weak or you have fits, **consult a doctor immediately**.
- Uramox may affect the liver and kidneys. If you experience pain in the lower back, pain or burning when passing urine, have difficulty in passing urine or you stop passing urine, have blood in your urine, pale stools, or if your skin or eyes look slightly yellow, **consult a doctor**. **In addition, contact a doctor** if your stools are black or tarry, or if you notice blood in your stools.

Additional side effects

Side effects whose frequency is unknown (frequency has not been established yet): headache; diarrhea; nausea or vomiting, loss of appetite, thirst, metallic taste in the mouth; dizziness, loss of full control of hands or legs; flushing; increased frequency of passing urine; tiredness or irritability; feeling overexcited; a feeling of numbness or tingling in the fingers or toes, or coldness in the extremities; depression; drowsiness or confusion; a loss of interest in sex; ringing in the ears or difficulty in hearing; temporary short-sightedness which subsides when the dosage is reduced or treatment is stopped; decrease in vision or pain in your eyes due to accumulation of fluid in the vascular layer of the eye (choroidal effusion or choroidal detachment).

Rare cases of skin rashes including an increased sensitivity to sunlight have been reported. If you experience any unusual skin rashes, inform your doctor.

When taking Uramox for a long time, the medicine can affect the level of potassium or sodium in your blood. Your doctor may perform blood tests to make sure that this is not happening.
With long-term therapy you might also experience bone thinning or be at risk of kidney stones.
High or low blood sugar levels may occasionally occur.

Consult a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (its frequency has not been established yet).

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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or 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 your doctor.
- Do not use the medicine after the expiry date (exp. date) that is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C.
- Shelf-life after first opening: 8 months.

- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

lactose monohydrate, corn starch, talc, gelatin, glycerin, sodium starch glycolate, magnesium stearate.

What the medicine looks like and contents of the pack:

white, round tablets, with “T53” written on one side and a score line on the other side.
Bottle of 30 tablets with a child-resistant cap.

Manufacturer and license holder’s name and address: Taro Pharmaceutical Industries Ltd., 14 Hakitor Street, Haifa Bay 2624761.

Registration number of the medicine in the Ministry of Health’s National Drug Registry:
016 94 21225 00

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