

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking AURO TORASEMIDE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **RISAT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

S3

RISAT 5 mg (Tablet)

RISAT 10 mg (Tablet)

Toraseamide anhydrous

1. WHAT RISAT CONTAINS

The active substance is toraseamide.

RISAT 5 mg: Each uncoated tablet contains toraseamide anhydrous 5 mg.

RISAT 10 mg: Each uncoated tablet contains toraseamide anhydrous 10 mg.

The other ingredients of **RISAT** are cellulose, microcrystalline, crospovidone, lactose monohydrate, magnesium stearate, and povidone.

2. WHAT RISAT IS USED FOR

Toraseamide belongs to a group of medicines called “diuretics” or “water tablets”. **RISAT** is used to reduce the swelling and fluid retention caused by heart or liver disease. It is also used to treat high blood pressure.

3. BEFORE YOU TAKE AURO TORASEMIDE

Do not take RISAT:

- If you have ever had an unusual or allergic reaction to sulfa medicines, toraseamide or any ingredient of the **RISAT**.
- If you have kidney problems (kidney failure) and if you are unable to urinate.

- If you have severe liver disease.
- If you are pregnant or breast-feeding.
- If you have a low volume of blood (hypovolaemia).
- If you have low levels of potassium or sodium in your blood.
- If you suffer from prostate problems or have difficulty passing water (urinating).
- **RISAT** must not be given to children of 12 years or younger.

Take special care with RISAT:

- Tell your doctor:
 - If you have or have ever had gout or high levels of uric acid in your blood.
 - If you have diabetes (diabetes mellitus).
- Signs of electrolyte and volume deficiency such as headache, dizziness, feelings of weakness, loss of appetite and cramps may occur, especially at the start of treatment or if you are an elderly patient.
- Keep all appointments with your doctor and the laboratory. Your blood pressure should be checked regularly, and blood tests should be done occasionally.

Taking RISAT with food and drink:

RISAT may be taken with some liquid, either with or without food.

Taking **RISAT** with alcohol may impair mental alertness.

Pregnancy and Breast-feeding:

Do not take **RISAT** if you are pregnant or planning a pregnancy or if you are breast-feeding.

Tell your doctor right away if you become pregnant during treatment.

If you are pregnant or breast - feeding your baby while taking **RISAT**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

RISAT may make you drowsy. Do not drive or use machinery until you know how **RISAT** affects you.

Important information about some of the ingredients of RISAT

RISAT contains lactose, which is a type of sugar. So before taking **RISAT**, please consult your doctor for advice if you have an intolerance to some sugars

Taking other medicines with RISAT:

Before taking **RISAT**, tell your doctor if you are using any of the following medicines:

- Digoxin heart medicine
- Steroid medicines such as hydrocortisone, prednisone and dexamethasone.
- Laxatives.
- Medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), such as indomethacin and ibuprofen.
- Other medicines to treat high blood pressure.
- Medicines used to treat diabetes.
- Aminoglycoside antibiotics, such as amikacin, gentamicin, netilmicin, streptomycin and tobramycin.
- Cephalosporin antibiotics, such as cephalexin and ceftriaxone.
- Cisplatin (used to treat cancer).
- Theophylline (used to treat asthma).
- Medicines to relax your muscles (muscle relaxants).
- Adrenaline (also called epinephrine) or noradrenaline (also called norepinephrine). These are used to treat low blood pressure.
- High doses of medicines called “salicylates”, such as aspirin.
- Cholestyramine (used to treat high levels of cholesterol in your blood).
- Lithium (used to treat mental health problems).
- Anticoagulants (used to treat blood clots).
- Probenecid (used to treat gout).

If you are using any of these medicines, you may not be able to take **RISAT**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **RISAT** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE RISAT

- Take **RISAT** only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor.

The usual dosages are as follows:

For the treatment of high blood pressure:

- The usual dose for adults is 2,5 mg once a day.
- Your doctor may increase the dose to 5,0 mg a day, if needed.

For the treatment of swelling and fluid retention caused by heart, liver and kidney problems:

- The usual dose for adults is 5,0 mg once a day.
- Your doctor may increase the dose up to 40,0 mg a day, if needed.

Always take **RISAT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **RISAT** is too strong or too weak, talk to your doctor or pharmacist.

If you take more RISAT than you should:

If you take too many tablets, you may pass a lot of urine, become sleepy, or feel confused, faint or dizzy. You may also have stomach upset.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take RISAT:

If you forget to take **RISAT**, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.

Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE-EFFECTS

RISAT can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Difficulty breathing.
- Swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side-effects:

- Low levels of sodium or potassium in you blood. This may cause headache, feeling dizzy, feeling weak, a loss of appetite or cramps. Your doctor may change your dose of **RISAT** if this happens.
- Reduced numbers of red or white blood cells or platelets in your blood. This may make you feel tired, get infections more easily, or bruise more easily.
- Problems with your circulation or blood clots may occur.
- Coughing up blood.
- Bloody or black, tarry stools.
- Ear or hearing problems.

Other side-effects include: Constipation, nausea, vomiting, diarrhoea, dry mouth, skin rashes and itchy skin, skin being more sensitive to the sun (photo-sensitivity), dizziness, headache, feeling numb or tingling in the legs or arms, confusion, difficulty passing water (urinating) in patients with prostate problems, changes in how your liver is working (shown by blood tests), and eye or eyesight problems. An increase in the levels of certain substances in your blood, including sugar, uric acid and fats (lipids) may occur.

Not all side-effects reported for **RISAT** are included in this leaflet. Should your general health worsen while taking **RISAT**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF RISAT

Store at or below 25 °C. Do not remove the blisters from the carton until required. Keep the bottle tightly closed.

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF RISAT

RISAT 5 mg AND RISAT 10 mg:

1. Blister Packs:

Tablets are packed in blister packs (composed of clear PVC film and silver coloured aluminium lidding foil). Each blister contains 10 tablets.

Pack size 30's: Each carton contains 3 blisters of 10 tablets each.

2. HDPE Container Pack:

Tablets are packed in white opaque HDPE containers.

Pack size: 30's: One HDPE container of 30 tablets.

Pack size: 500's: One HDPE container of 500 tablets.

8. IDENTIFICATION OF RISAT

RISAT 5 mg:

White to off-white, oval shaped, biconvex, uncoated tablets debossed with 'C' on one side and with a score line in between '4' and '1' on the other side.

RISAT 10 mg:

White to off-white, oval shaped, biconvex, uncoated tablets debossed with 'C' on one side and with a score line in between '4' and '2' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

RISAT 5 mg: 43/18.1/1042

RISAT 10 mg: 43/18.1/1043

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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