RISAT
P1532686

RISAT
P1532686

SCHEDULING STATUS

SOUTH AFRICA: S3

NAMIBIA: NS2

PROPRIETARY NAME (and dosage form):
RISAT 5 mg (Tablet)
RISAT 10 mg (Tablet)

COMPOSITION:
RISAT 5 mg:
Each uncoated tablet contains torasemide anhydrous 5 mg. Contains sugar: 79 mg lactose.

RISAT 10 mg:
Each uncoated tablet contains torasemide anhydrous 10 mg. Contains sugar: 158 mg lactose.
The other ingredients of **RISAT** are cellulose microcrystalline, crospovidone, magnesium stearate and povidone.

PHARMACOLOGICAL CLASSIFICATION:
A 18.1 Diuretics

PHARMACOLOGICAL ACTION:
Torasemide is a salidiuretic. It inhibits renal sodium and chloride re-absorption in the ascending limb of Henlé. The action may last up to 12 hours. An increase in dose results in a corresponding linear increase in urine excretion (high ceiling activity) in healthy subjects in the 5 mg to 10 mg dose range.

After oral administration the blood pressure lowering effect of torasemide starts within the first week of treatment, the maximum effect being achieved after about 12 weeks.

The exact mechanism of action of antihypertensive treatment with torasemide has not been established.

Pharmacokinetics:
After oral administration, torasemide is absorbed rapidly and almost completely and peak serum levels are reached after 1 to 2 hours. More than 99 % of torasemide is bound to plasma proteins. The apparent distribution volume is 16 litres. Bioavailability is 80 % to 90 %. In healthy subjects, the terminal half-life of torasemide is 3 to 4 hours. Total clearance is 40 ml/min and renal clearance about 10 ml/min.

Special populations:
In patients with congestive heart failure or disorder of liver function the elimination half-life of torasemide is prolonged compared with healthy volunteers, but quantities excreted in the urine correspond to those in healthy subjects. The elimination half-life of torasemide is unchanged in the presence of renal failure. The duration of action is not influenced and pharmacodynamic behaviour is not affected by the severity of renal failure.

INDICATIONS:
RISAT tablets are indicated in:
- Essential hypertension.
- Oedema of cardiac and hepatic origin.
- Pulmonary oedema due to acute cardiac insufficiency.

CONTRA-INDICATIONS:
RISAT tablets are contra-indicated in:
- Hypersensitivity to torasemide or any of the ingredients of **RISAT.**
- Renal failure with absence of urine production (anuria).
- Hepatic failure.
- During pregnancy and lactation.
- Patients with known hypersensitivity to sulfonylureas.
- Hypovolaemia.
- Hyponatraemia, hypokalaemia.
- Severe disorders of micturition (e.g. prostate hypertrophy).

Due to lack of clinical experience, **RISAT** should not be used in children of 12 years or younger.

WARNINGS AND SPECIAL PRECAUTIONS:
Signs of electrolyte imbalance and volume depletion such as headache, dizziness, weakness, loss of appetite and cramps may occur, if diuresis is excessive, especially at the start of treatment and in elderly patients.

When used simultaneously with digoxin, potassium and/or magnesium deficiency may increase the sensitivity of the cardiac muscle to digoxin.

The effect of antihypertensive medicines may be potentiated, such as in the consecutive treatment or start of a new co-medication with an angiotensin converting enzyme inhibitor may result in an excessive fall in blood pressure.

In patients with a tendency to hyperuricaemia and gout, careful monitoring is required.

As a rise in blood glucose may occur, careful monitoring of the carbohydrate metabolism in patients with latent or manifest diabetes mellitus is recommended.

In patients with urinary obstructions, e.g. prostate hypertrophy, increased urine production can lead to urine retention resulting in distension of the bladder.

RISAT contains lactose and should not be given to patients with rare hereditary problems or a history of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

In patients receiving high doses of salicylates, salicylate-toxicity may be increased.

Ability to drive and use of machinery:
Individually varying reactions can impair alertness, (e.g. patient's ability to operate machinery or drive vehicles). This applies particularly when beginning treatment, switching from another medicine or starting a new co-medication and in conjunction with alcohol.

INTERACTIONS:
- The kalidiuretic effect of mineralo - and glucocorticosteroids and laxatives may be increased.
- The effect of **RISAT** may be reduced by nonsteroidal anti-inflammatory medicines (NSAIDs).
- The action of antidiabetic medicines may be reduced.
- Torasemide may potentiate the damaging effects of aminoglycoside antibiotics, cisplatin preparations and cephalosporins on the ear and kidney especially at high dose therapy.
- The action of theophylline and of curare containing muscle relaxants can be potentiated.
- The arterial responsiveness to pressor agents, e.g. epinephrine (adrenaline) and norepinephrine (noradrenaline) may be decreased by torasemide.
- On concomitant treatment with cholestyramine, bioavailability and therefore the effectiveness of **RISAT** may be reduced.
- Concurrent use with antidysrhythmic medicines may lead to an increased risk of dysrhythmias associated with hypokalaemia.
- When **RISAT** and anticoagulants are used concurrently, the effects of the anticoagulants may be decreased.
- Because of reduced renal clearance, concomitant use with lithium may promote lithium toxicity.
- Probenecid may decrease the activity of torasemide.

PREGNANCY AND LACTATION:
RISAT is contra-indicated in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:
Essential hypertension:
Treatment is initiated with 2, 5 mg **RISAT** per day. The usual maintenance dose is 2, 5 mg per day. If this is insufficiently effective, the dose can be doubled to 5 mg per day. Higher doses will not lead to a further reduction of blood pressure.

Oedema of cardiac, hepatic and renal origin:
Treatment is initiated with 5 mg torasemide per day. The usual maintenance dose is 5 mg per day. If this is insufficiently effective, the dose can be increased up to 20 mg per day depending on the severity of the disease. In individual cases as much as 40 mg torasemide per day has been administered. **RISAT** may be taken with or without meals.

SIDE EFFECTS:
Metabolic and nutrition disorders:
Less frequent:
Disturbances of water and electrolyte balance, especially with limited salt intake.

Hypokalaemia, hyponatraemia and hypochloraemic alkalosis.

Blood and lymphatic system disorders:
Less frequent:
A decrease in the erythrocyte, leucocyte and platelet counts.

AUROGEN

Vascular disorders:
Less frequent:
Hypotension.

The following side effect has been reported and frequency is unknown:
Thromboembolic complications.

Cardiac disorders:
The following side effects have been reported and frequencies are unknown:
Cardiac or cerebral ischaemia.

Gastrointestinal disorders:
Frequent:
Constipation, nausea and vomiting

Less frequent:
Gastrointestinal haemorrhage and dry mouth.

The following side effect has been reported and frequency is unknown:
Diarrhoea.

Renal and urinary disorders:
The following side effects have been reported and frequencies are unknown:
Increase in blood urea and creatinine, even in clinically healthy kidneys or in the presence of damaged kidneys.

Skin and subcutaneous tissue disorders:
Less frequent:
Allergic skin reactions, e.g. pruritus and exanthema or photosensitisation.

Nervous system disorders:
Frequent:
Dizziness and headache.

Less frequent:
Paraesthesia in the limbs.

The following side effects have been reported and frequencies are unknown:
Due to haemoconcentration after marked diuresis, confusional states may occur.

Eye disorders:
Less frequent:
Visual disturbances.

Ear and labyrinth disorders:
Less frequent:
Ototoxicity.

Investigations:
The following side effects have been reported and frequencies are unknown:
Increases in Gamma-GT, alteration in the blood glucose and lipid metabolism, a rise in the uric acid level.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
If overdosage occurs there may be a marked diuresis with the danger of loss of liquids and electrolytes which may lead to somnolence and confusion, hypotension, circulatory collapse and gastrointestinal symptoms. There is no known specific antidote.

Symptoms of overdosage generally disappear on reduction of the dose or withdrawal of the medication and simultaneous replacement of fluid and electrolytes (to be monitored).

IDENTIFICATION:
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.

PRESENTATION:
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.

STORAGE INSTRUCTIONS
Store at or below 25 °C.

Do not remove the blisters from the carton until required.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

SOUTH AFRICA:
RISAT 5 mg: 43/18.1/1042
RISAT 10 mg: 43/18.1/1043

NAMIBIA:
RISAT 5 mg: 20/18.1/0154
RISAT 10 mg: 20/18.1/0155

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, Johannesburg,
South Africa, 1448

DATE OF PUBLICATION OF THE PACKAGE INSERT:
02 June 2017

DATE OF REVISION:
13 December 2022

DETACH BEFORE DISPENSING

SOUTH AFRICA: S3

NAMIBIA: NS2

RISAT 5 mg (Tablet)
RISAT 10 mg (Tablet)
Torasemide anhydrous

Read all of this leaflet carefully before you start taking RISAT.
- 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.

1. WHAT RISAT CONTAINS:
The active substance is torasemide.
RISAT 5 mg: Each uncoated tablet contains torasemide anhydrous 5 mg. Contains sugar: 79 mg lactose.
RISAT 10 mg: Each uncoated tablet contains torasemide anhydrous 10 mg. Contains sugar: 158 mg lactose.
The other ingredients of **RISAT** are cellulose microcrystalline, crospovidone, magnesium stearate and povidone.

2. WHAT RISAT IS USED FOR:
Torasemide 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 RISAT:
Do not take RISAT:
- If you have ever had an unusual or allergic reaction to sulfa medicines, torasemide 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 breastfeeding.
- 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 Breastfeeding:
Do not take **RISAT** if you are pregnant or planning a pregnancy or if you are breastfeeding. Tell your doctor right away if you become pregnant during treatment.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking **RISAT.**

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.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

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 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 mg once a day.
- Your doctor may increase the dose up to 40 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, feel confused, faint or dizzy. You may also have an upset stomach.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 or if you experience any untoward effects while taking **RISAT,** please consult your doctor, pharmacist or other healthcare 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.

Store 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.
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8. IDENTIFICATION OF RISAT:
RISAT 5 mg:
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RISAT 10 mg:
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9. REGISTRATION NUMBER/REFERENCE NUMBER:

SOUTH AFRICA:
RISAT 5 mg: 43/18.1/1042
RISAT 10 mg: 43/18.1/1043

NAMIBIA:
RISAT 5 mg: 20/18.1/0154
RISAT 10 mg: 20/18.1/0155

10. NAME AND ADDRESS OF REGISTRATION HOLDER:
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, Johannesburg,
South Africa, 1448

11. DATE OF PUBLICATION:
02 June 2017

DATE OF REVISION:
13 December 2022

SKEDULERINGSTATUS

SUID-AFRIKA: S3

NAMIBIË: NS2

EIENDOMSNAAM (en doseervorm):

RISAT 5 mg (Tablet)
RISAT 10 mg (Tablet)

SAMESTELLING:
RISAT 5 mg:
Elke onbedekte tablet bevat anhidriese torasemied 5 mg. Bevat suiker: 79 mg laktose.

RISAT 10 mg:
Elke onbedekte tablet bevat anhidriese torasemied 10 mg. Bevat suiker: 158 mg laktose.

Die ander bestanddele van **RISAT** is mikrokristallyne sellulose, krospovidoon, magnesiumstearaat en povidoon.

FARMAKOLOGIESE KLASSIFIKASIE:
A 18.1 Diuretika

FARMAKOLOGIESE WERKING:
Torasemied is 'n salidiuretikum. Dit inhibeer die heropname van natrium en chloried in die buis van Henle in die niere. Hierdie werking kan tot 12 ure duur. 'n Toename in die dosis lei tot 'n ooreenstemmende lineêre toename in urienuitskeiding (hoë plafonaktiwiteit) in gesonde indiwidue in die 5 mg tot 10 mg dosisreikwydte.

Na orale toediening begin die bloeddrukverlagende effek van torasemied binne die eerste week van behandeling, met die maksimum effek wat na ongeveer 12 weke bereik word.

Die presiese meganisme van antihipertensiewe terapie met torasemied is nie vasgestel nie.

Farmakokinetika:
Na orale toediening word torasemied vinnig en byna volledig geabsorbeer en piek serumvlakke word na ongeveer 1 tot 2 ure bereik. Meer as 99 % van torasemied word aan plasmaproteïene gebind. Die oënskynlike volume van verspreiding is 16 liter. Die biobeskikbaarheid is 80 % tot 90 %. In gesonde indiwidue is die terminale halfleeftyd van torasemied 3 tot 4 ure. Die totale opruiming is 40 ml/min en nieropruiming is 10 ml/min.

Spesiale populasies:
In pasiënte met kongestiewe hartversaking of 'n afwyking in lewerfunksie is die opruimingshalfleeftyd langer as in gesonde vrywilligers, alhoewel die hoeveelhede wat in die urien uitgeskei word ooreenstem met dié in gesonde vrywilligers. Die opruimingshalfleeftyd van torasemied bly onveranderd in die teenwoordigheid van nierversaking. Die duurte van werking word nie beïnvloed nie en die farmakodinamiese gedrag word nie deur die graad van erns van nierversaking beïnvloed nie.

INDIKASIES:
RISAT tablette word aangedui vir:
- Essensiële hipertensie.
- Edeem van hart- of leweroorsprong.
- Longedeem weens akute hartontoereikendheid.

KONTRA-INDIKASIES:
RISAT tablette word teenaangedui in:
- Hipersensitiwiteit teen torasemied of enige van die bestanddele van **RISAT**.
- Nierversaking met die afwesigheid van urienproduksie (anurie).
- Lewerversaking.
- Swangerskap en laktasie.
- Pasiënte met 'n bekende hipersensitiwiteit teen sulfonilureas.
- Hipovolumie.
- Hiponatremie, hipokalemie.
- Erge urienlatingsafwykings (bv. hipertrofie van die prostaat).

Weens 'n tekort aan kliniese ondervinding behoort **RISAT** nie in kinders jonger as 12 jaar oud gebruik te word nie.

WAARSKUWINGS EN SPESIALE VOORSORGSMATREELS:
Tekens van elektrolietwanbalans en volume-uitputting soos hoofpyn, duiseligheid, swakheid, verlies aan eetlus en krampe mag voorkom as diurese oormatig is, veral aan die begin van behandeling en in bejaarde pasiënte.

Wanneer saam met digoksien gebruik word, kan 'n tekort aan kalium en magnesium die sensitiwiteit van die hartspier teen digoksien verhoog.

Die effek van antihipertensiewe medisyne mag versterk word, soos opeenvolgende behandeling of die begin met 'n nuwe ko-medikasie met 'n angiotensienomskakelingsensiem-inhibeerders kan tot 'n oormatige afname in bloeddruk lei.

In pasiënte wat hoë salisilaatdosisse ontvang, kan salisilaattoksisiteit toeneem.

In pasiënte wat tot hiperurisemie en jig neig, word noukeurige monitering vereis.

Aangesien 'n toename in bloedglukose kan voorkom, word noukeurige monitering van die koolhidraatmetabolisme in pasiënte met latente of gemanifesteerde diabetes mellitus aanbeveel.

In pasiënte met urienwegobstruksie bv. hipertrofie van die prostaat, kan 'n toename in urienproduksie tot urienretensie en gevolglik tot distensie van die blaas lei.

RISAT bevat laktose en behoort nie aan pasiënte met selde voorkomende oorerflike probleme of 'n geskiedenis van galaktose intoleransie, Lapp-laktasetekort of glukose-galaktose wanabsorpsie toegedien te word nie.

Die vermoë om te bestuur of met masjinerie te werk:
Indiwidueel wisselende reaksies kan skerpheid (bv. die vermoë om met masjinerie te werk of voertuig te bestuur) inkort. Dit geld veral wanneer daar met behandeling begin word, wanneer daar van ander middels oorgeskakel word, of wanneer daar met nuwe ko-medikasie begin word, asook met die inname alkohol.

INTERAKSIES:
- Die kalidiuretiese effek van mineralo- en glukokortikosteroïede en lakseermiddels kan toeneem. Die effek van **RISAT** kan deur nie-steroïed anti-inflammatoriese middels (NSIAMs) verminder word.
- Die werking van antidiabetiese medisyne mag verminder word.
- Torasemied kan die skadelike effekte van aminoglikosiedantibiotika, sisplatienpreparate en kefalosporiene op die oor en nier versterk, veral teen hoë dosisse.
- Die werking van teofillien en kurarebevattende spierverslappers mag versterk word.
- Die arteriële respons tot pressormiddels bv. epinefrien (adrenalien) en norepinefrien (noradrenalien) kan deur torasemied verminder word.
- Die meegaande behandeling met cholestiramien kan die biobeskikbaarheid en derhalwe die effektiwiteit van **RISAT** verminder.
- Die meegaande gebruik van antidisritmiese middels kan tot 'n toename in die risiko van disritmieë wat met hipokalemie gepaard gaan, lei.
- Wanneer **RISAT** en antistolmiddels saam gebruik word, kan die effek van die antistolmiddels afneem.
- Weens 'n afname in nieropruiming, kan die gelyktydige gebruik saam met litium, litiumtoksisiteit bevorder.
- Probenesied kan die effek van torasemied verminder.

SWANGERSKAP EN LAKTASIE:
RISAT word teenaangedui in swangerskap en laktasie.

DOSIS EN GEBRUIKSAANWYSINGS:
Essensiële hipertensie:
Behandeling word begin met 2,5 mg **RISAT** per dag. Die normale onderhoudsdosis is 2,5 mg per dag. As dit nie voldoende effektief is nie, kan die dosis na 5 mg per dag verdubbel word. Hoër dosisse sal nie tot 'n verdere verlaging in bloeddruk lei nie.

Edeem van hart-, lewer- of nieroorsprong:
Behandeling word begin met 5 mg **RISAT** per dag. Die normale onderhoudsdosis is 5 mg per dag. As dit nie voldoende effektief is nie, kan die dosis na 20 mg per dag verhoog word, afhangende van die graad van erns van die siekte. In indiwiduele gevalle is soveel as 40 mg torasemied per dag toegedien. **RISAT** kan met of sonder maaltye geneem word.

NEWE EFEFKTE:
Metaboliese en voedingsafwykings:
Minder dikwels:
Afwykings van water- en elektrolietbalans, veral met beperkte soutinname.

Hipokalemie, hiponatremie en hipochloremiese alkalose.

Afwykings van die bloed- en limfsisteem:
Minder dikwels:
'n Afname in die eritrosiet-, leukosiet- en plaatjietellings.

Vaskulêre afwykings:
Minder dikwels:
Hipotensie.

Die newe effek is aangemeld en die frekwensie is onbekend:
Tromboëmboliese komplikasies.

Hartafwykings:
Die newe effekte is aangemeld en die frekwensies is onbekend:
Hart- of serebrale iskemie.

Gastroïntestinale afwykings:
Dikwels:
Hardlywigheid, naarheid en braking.

Minder dikwels:
Gastroïntestinale bloeding en droë mond.

Die newe effek is aangemeld en die frekwensie is onbekend:
Diarree.

Nier- en urienafwykings:
Die newe effekte is aangemeld en die frekwensies is onbekend:
'n Toename in bloedurea en -kreatinien, selfs in klinies gesonde niere of in die teenwoordigheid van beskadigde niere.

Afwykings van die vel en subkutane weefsel:
Minder dikwels:
Allergiese velreaksies bv. pruritus en eksanteem of fotosensitering.

Afwykings van die senuweestelsel:
Dikwels:
Duiseligheid en hoofpyn.

Minder dikwels:
Parestesie in die ledemate.

Die newe effekte is aangemeld en die frekwensies is onbekend:
Weens hemokonsentrasie na merkbare diurese, kan verwardheid voorkom.

Oogafwykings:
Minder dikwels:
Gesigsafwykings.

Afwykings van die oor en labirint:
Minder dikwels:
Ototoksisiteit.

Ondersoeke:
Die volgende is aangemeld en die frekwensies is onbekend:
Toename in gamma-GT, verandering in bloedglukose- en lipiedmetabolisme, 'n toename in uriensuurkonsentrasie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Indien oordosering plaasvind, kan dit met merkbare diurese en die gevaar van 'n verlies aan vloeistof en elektroliete wat tot slaapsug en verwardheid kan lei, hipotensie, sirkulatoriese insinking en gastroïntestinale simptome kan lei. Daar bestaan geen bekende teenmiddel nie.

Simptome van oordosering verdwyn oor die algemeen met vermindering of staking van die middel en die gelyktydige vervanging van vloeistof en elektroliete (wat gemonitor moet word).

IDENTIFIKASIE:
RISAT 5 mg:
Wit tot byna-wit, ovaalvormige, bikonvekse, onbedekte tablette met 'C' op die een kant en '4' en '1' op die ander kant gedruk, verdeel deur 'n breeklyn.

RISAT 10 mg:
Wit tot byna-wit, ovaalvormige, bikonvekse, onbedekte tablette met 'C' op die een kant en '4' en '2' op die ander kant gedruk, verdeel deur 'n breeklyn.

AANBIEDING:
RISAT 5 mg en **RISAT 10 mg:**
1. Stolpverpakking:
Tablette word in stolpstrokies verpak (bestaande uit helder PVC film en silwergekleurde aluminium deklaag). Elke strokie bevat 10 tablette.

Pakgrootte: 30's - Elke karton bevat 3 strokies van 10 tablette elk.

2. HDPE Verpakking:
Tablette word in wit, ondeursigtige HDPE houers verpak.

Pakgrootte: 30's - Een HDPE houer bevat 30 tablette.

Pakgrootte: 500's - Een HDPE houer bevat 500 tablette.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 25 °C.
Moenie die strokies uit die karton verwyder tot voor gebruik nie.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS:

SUID-AFRIKA:
RISAT 5 mg: 43/18.1/1042
RISAT 10 mg: 43/18.1/1043

NAMIBIË:
RISAT 5 mg: 20/18.1/0154
RISAT 10 mg: 20/18.1/0155

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1 Eerste Vloer
Phillip Engelbrechtlaan 53,
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1448, Suid Afrika.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
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13 Desember 2022

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DETACH BEFORE DISPENSING

SUID-AFRIKA: S3

NAMIBIË: NS2

RISAT 5 mg (Tablet)
RISAT 10 mg (Tablet)
Anhidriese torasemied

Lees die hele brosjure sorgvuldig voordat u begin om RISAT te neem.
- Hou hierdie bladdjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **RISAT** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT RISAT BEVAT:
Die aktiewe bestanddeel is torasemied.

RISAT 5 mg: Elke onbedekte tablet bevat anhidriese torasemied 5 mg. Bevat suiker: 79 mg laktose.

RISAT 10 mg: Elke onbedekte tablet bevat anhidriese torasemied 10 mg. Bevat suiker: 158 mg laktose.

Die ander bestanddele van **RISAT** is mikrokristallyne sellulose, krospovidoon, magnesiumstearaat en povidoon.

2. WAARVOOR RISAT GEBRUIK WORD:
Torasemied behoort aan 'n groep van medisyne wat "diuretika" of "watertablette" genoem word. **RISAT** word gebruik om die swelling en vloeistofretensie wat deur hart- of lewersiekte veroorsaak word, te verminder. Dit word ook gebruik om hoë bloeddruk te behandel.

3. VOORDAT U RISAT GEBRUIK:
Moenie RISAT gebruik nie:
- As u al ooit 'n ongewone of allergiese reaksie teen sulfamedisyne, torasemied of enige van die bestanddele van **RISAT** gehad het.
- As u aan nierprobleme (nierversakking) ly en as u nie kan urineer nie.
- As u aan 'n lewersiekte ly.
- As u swanger is of borsvoed.
- As u aan 'n lae bloedvolume (hipovolumie) ly.
- As die kalium- of natriumvlakke in u bloed laag is.
- As u aan prostaatprobleme ly of as u moeite het om te urineer.
- **RISAT** moet nie aan kinders jonger as 12 jaar oud toegedien word nie.

Neem spesiale sorg met RISAT:
- Stel u dokter in kennis:
  - As u ooit aan jig of hoë uriensuurvlakke in u bloed gely het.
  - As u aan diabetes (diabetes mellitus) ly.
- Tekens van elektroliet- en volumetekort soos hoofpyn, duiseligheid, swakheid, verlies aan eetlus en krampe mag voorkom, veral aan die begin van behandeling of as u 'n bejaarde pasiënt is.
- Hou alle afsprake met u dokter en laboratorium. U bloeddruk behoort gereeld nagegaan te word en bloedtoetse behoort af en toe uitgevoer te word.

Die neem van RISAT met voedsel en vloeistof:
RISAT kan saam met vloeistof, met of sonder voedsel geneem word.
Die gebruik van **RISAT** saam met alkohol kan geestelike skerpheid inkort.

Swangerskap en borsvoeding:
Moenie **RISAT** neem as u swanger is of beplan om swanger te raak nie en ook nie as u borsvoed nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies nader voordat u **RISAT** neem.

Bestuur en die gebruik van masjinerie:
RISAT kan u lomerig maak. Moenie bestuur of met masjinerie werk nie totdat u weet hoe **RISAT** u affekteer.

Belangrike inligting oor sommige van die bestanddele van RISAT:
RISAT bevat laktose wat 'n soort suiker is. Voordat u **RISAT** neem, raadpleeg asseblief u dokter vir advies as u intolerant teen sekere suikers is.

Die neem van ander medisyne saam met RISAT:
Voordat u **RISAT** gebruik, moet u u dokter in kennis stel as u enige van die volgende medisyne gebruik:
- Digoksien (hartmedisyne).
- Steroïedmedisyne soos hidrokortisoon, prednisoon en deksametasoon.
- Lakseermiddels.
- Medisyne wat "nie-steroïed anti-inflammatoriese middels" (NSAIMs) genoem word, soos indometasien en ibuprofen.
- Ander middels om hoë bloeddruk te behandel.
- Medisyne om diabetes te behandel.
- Aminoglikosiedantibiotika soos amikasien, gentamisien, streptomisien en tobramisien.
- Kefalosporienantibiotika soos kefaleksien en keftriaksoon.
- Sisplatien (gebruik om kanker te behandel).
- Teofillien (gebruik om asma te behandel).
- Medisyne om u spiere te verslap (spierverslappers).
- Adrenalien (ook epinefrien genoem) of noradrenalien (ook norepinefrien genoem).
- Hierdie middels word gebruik om lae bloeddruk te behandel.
- Hoë dosisse van middels wat "salisilate" genoem word, soos aspirien.
- Cholestiramien (gebruik om hoë cholesterolvlakke in die bloed te behandel).
- Litium (gebruik om geestessiekte te behandel).
- Antistolmiddels (gebruik om bloedklonte te behandel).
- Probenesied (gebruik om jig te behandel).

As u enige van hierdie medisyne gebruik, mag u moontlik nie **RISAT** kan gebruik nie, of u dosis moet aangepas word of u dokter mag besluit om u noukeurig vir newe effekte te monitor.

Stel altyd u dokter in kennis as u enige ander medisyne gebruik.
(Dit sluit komplementêre of tradisionele medisyne in).

4. HOE OM RISAT TE NEEM:
- Neem **RISAT** slegs soos deur u dokter voorgeskryf.
- Moenie meer of minder gebruik nie en moenie dit meer dikwels as deur u dokter voorgeskryf, neem nie.

Die normale dosis is as volg:
Vir die behandeling van hoë bloeddruk:
- Die normale dosis vir volwassenes is 2,5 mg een keer per dag
- U dokter mag die dosis na 5 mg een keer per dag verhoog, indien nodig

Vir die behandeling van swelling en vloeistofretensie veroorsaak deur hart-, lewer- en nierprobleme:
- Die normale dosis vir volwassenes is 5 mg per dag.
- U dokter mag die dosis na 40 mg per dag verhoog, indien nodig.

Neem **RISAT** altyd presies soos deur u dokter voorgeskryf. As u onder die indruk is dat die effek van **RISAT** te sterk of te swak is, moet u asseblief u dokter of apteker raadpleeg.

As u te veel RISAT geneem het:
As u te veel tablette geneem het, mag u baie begin urineer, lomerig raak en verward of duiselig voel. U mag ook 'n omgekrapte maag ontwikkel.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of giftebeheersentrum.

As u vergeet het om RISAT te neem:
As u vergeet het om **RISAT** te neem, moet u dit so gou as wat u daarvan onthou, neem. Indien dit egter byna tyd vir u volgende dosis is, slaan die dosis oor en gaan voort met u dosisskedule. Moenie die dosis verdubbel om vir 'n oorgeslaande dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE:
RISAT kan newe effekte hê.

Kry nood mediesehulp as u enige van hierdie tekens van 'n allergiese reaksie ondervind:
- Moeite met asemhaling.
- Swelling van u gesig, lippe. tong of keel.

Raadpleeg onmiddellik u dokter as u enige van die volgende ernstige newe effekte ondervind:
- Lae natrium- of kaliumvlakke in u bloed. Dit kan hoofpyn, duiseligheid, swakheid, verlies aan eetlus of krampe insluit. U dokter mag die dosis **RISAT** verander as dit voorkom.
- 'n Afname van die aantal rooi- of witbloedselle of plaatjies in u bloed. Dit mag u laat moeg voel, vinniger infeksies laat opdoen of u kan vinnige kneus.
- Probleme met u sirkulasie of bloedklonte mag voorkom.
- Ophoes van bloed.
- Bloederige, swart teeragtige stoelgang.
- Eet- of gehoorprobleme.

Ander newe effekte sluit die volgende in: hardlywigheid, naarheid, braking, diarree, droë mond, veluitslag en jeukerige vel, 'n vel wat meer sensitief teen die son is (fotosensitiwiteit), duiseligheid, hoofpyn, gevoelloosheid of prikkeling in die bene of arms, verwardheid, moeite om te urineer in pasiënte met prostaatprobleme, verandering in lewerfunksie (aangetoon deur bloedtoetse) en oog- of gesigsprobleme. 'n Toename in sekere substanse in die bloed insluitende suiker, uriensuur en vette (lipiede) mag voorkom.

Nie al die newe effekte wat vir **RISAT** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **RISAT** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg

6. OPBERGING EN WEGDOEN VAN RISAT:
Bewaar teen of benede 25 °C. Moenie die stolpstrokies uit die karton haal tot voor gebruik nie.

Berg alle medisyne buite die bereik van kinders.

Neem alle ongebruikte medisyne na u apteker terug
Moenie ongebruikte medisyne in die rioleringstelsel (bv. toilet) wegdoen nie.

7. AANBIEDING VAN RISAT:
RISAT 5 mg en **RISAT 10 mg:**
1. Stolpverpakkings:
Tablette word in stolpstrokies (bestaande uit helder PVC film en 'n silwergekleurde aluminiumfoelie deklaag) verpak. Elke strokie bevat 10 tablette.

Pakgrootte: 30's Elke karton bevat 3 strokies van 10 tablette elk.

2. HDPE Houer:
Tablette word in wit ondeursigtige HDPE houers verpak.

Pakgrootte: 30's -Een HDPE houer bevat 30 tablette.

Pakgrootte: 500's -Een HDPE houer bevat 500 tablette.

8. IDENTIFIKASIE VAN RISAT:
RISAT 5 mg:
Wit tot byna-wit, ovaalvormige, bikonvekse, onbedekte tablette met 'C' op die een kant en '4' en '1' op die ander kant gedruk, verdeel deur 'n breeklyn.

RISAT 10 mg:
Wit tot byna-wit, ovaalvormige, bikonvekse, onbedekte tablette met 'C' op die een kant en '4' en '2' op die ander kant gedruk, verdeel deur 'n breeklyn.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER:

SUID-AFRIKA:
RISAT 5 mg: 43/18.1/1042
RISAT 10 mg: 43/18.1/1043

NAMIBIË:
RISAT 5 mg: 20/18.1/0154
RISAT 10 mg: 20/18.1/0155

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER:
AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1 Eerste Vloer
Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, Johannesburg,
1448, Suid Afrika.

11. DATUM VAN PUBLIKASIE:
02 Junie 2017

DATUM VAN HERSIENING:
13 Desember 2022