

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*
Product Proprietary Name: *REDURIC 100 & 300*
Dosage Form & Strength: *Tablets, (Allopurinol 100 mg & Allopurinol 300 mg)*

SCHEDULING STATUS: **S3**

REDURIC 100

Allopurinol 100 mg tablets

REDURIC 300

Allopurinol 300 mg tablets.

Contains sugar

REDURIC 100: Lactose monohydrate 30,53 mg

REDURIC 300: Lactose monohydrate 90,10 mg

Read all this leaflet carefully before you start taking REDURIC.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **REDURIC** 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.

What is in this leaflet:

1. What **REDURIC** is and what it is used for
2. What you need to know before you take **REDURIC**
3. How to take **REDURIC**
4. Possible side effects
5. How to store **REDURIC**
6. Contents of the pack and other information



1. What REDURIC is and what it is used for

REDURIC contain a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body to lower the level of uric acid in your blood and urine.

REDURIC is used to reduce or prevent the formation of urate/uric acid deposition in conditions where your body produces too much of a substance called uric acid. These may include gout or some types of kidney stones, or certain other types of kidney problems, or when you are having treatment for cancer or some other conditions. In gout the uric acid builds up in your joints and tendons as crystals. These crystals cause an inflammatory reaction. The inflammation causes the skin around certain joints to become swollen, tender and sore when only slightly touched. You can also find you get severe pain when the joint is moved.

2. What you need to know before you take REDURIC

Do not take REDURIC:

- If you are hypersensitive (allergic) to allopurinol or any of the other ingredients of **REDURIC** (see What **REDURIC** contains). If you have a severe kidney or liver problem.
- If you are currently having an acute attack of gout.
- Children, except those diagnosed with a certain type of cancer.
- If you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with REDURIC:



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- **REDURIC** treatment should be stopped immediately if any skin rash or allergic reaction occurs. Contact your doctor for advice if you develop a skin rash once starting treatment with **REDURIC**.
- If you have a liver or kidney disorder.
- If you suffer from high blood pressure or a heart disorder and you are taking medicines to treat these conditions, such as diuretics or ACE inhibitors.
- **REDURIC** should not be used to treat an acute attack of gout. **REDURIC** may cause an acute attack when starting treatment initially. Your doctor may prescribe additional medicines during the first month of **REDURIC** treatment.
- If you have cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to assure to drink fluids sufficiently to dilute your urine.
- If you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.
- If you have thyroid problems.

Other medicines and REDURIC:

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

Tell your doctor or pharmacist if you are currently using:

- Vidarabine (used to treat herpes or chickenpox).
- Medicines used in the treatment of certain types of cancers, such as mercaptopurine, azathioprine and other anti-neoplastic medicines.
- Medicines that can increase uric acid concentration, such as aspirin or other salicylates (used for pain and inflammation).



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- Chlorpropamide (used to treat diabetes).
- Medicines used to thin your blood (anticoagulants), such as warfarin.
- Phenytoin (used to treat epilepsy).
- Theophylline (used for breathing problems).
- Ampicillin or amoxicillin (antibiotics used to treat bacterial infections).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Didanosine (used to treat HIV/AIDS).
- Medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics).
- Antacids (used to treat heartburn or indigestion).
- Aluminium hydroxide and **REDURIC** should not be taken together. There should be an interval of at least 3 hours between taking both medicines.

REDURIC with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **REDURIC**.

Do not take **REDURIC** during pregnancy or breastfeeding (see section 2).



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Driving and using machines

REDURIC can cause side effects, such as changes in eyesight, drowsiness, dizziness and coordination problems and can interfere with your ability to drive a vehicle or operate machinery. If this happens to you, do not engage in activities which require you to be alert; for example, driving a car and using machinery.

It is not always possible to predict to what extent **REDURIC** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activity until they are aware of the measure to which **REDURIC** affects them.

REDURIC contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take REDURIC

Do not share medicines prescribed for you with any other person.

Always take **REDURIC** exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults:

Gout: The usual dose is 50 mg twice daily, and then to increase this dose as required up to 200 mg to 400 mg daily in divided doses. Your doctor will decide on the correct dose, depending on your body's response.



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Hyperuricaemia associated with leukaemia: The initial dose is 200 mg three times daily, starting, if possible, 2 or 3 days before radiotherapy. The usual maintenance dose is 300 mg to 400 mg daily.

Children:

Your doctor will determine the dose based upon the weight of your child.

You should take adequate amounts of fluid (at least 2 litres) during the day while on treatment with **REDURIC**.

REDURIC can be taken with or without food.

Your doctor will tell you how long your treatment with **REDURIC** will last. If you have the impression that the effect of **REDURIC** is too strong or too weak, tell your doctor or pharmacist.

If you take more REDURIC than you should

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

Take this leaflet and the rest of the remaining **REDURIC** with you so the doctor will know what you have taken.

If you forget to take REDURIC

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **REDURIC** at the next regularly scheduled time.



Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

REDURIC can have side effects.

Not all side effects reported for **REDURIC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **REDURIC**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **REDURIC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **REDURIC**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- Rash
- Increased thyroid levels when blood tests are done.



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Less frequent side effects:

- Boils (red, raised bumps on your skin caused by infection around the hair follicles).
- Anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration).
- Vasculitis (inflammation of your blood vessels, which can cause fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness).
- High blood sugar levels (diabetes).
- High levels of cholesterol in your blood (hyperlipidaemia).
- Drowsiness or sleepiness.
- Being in a sad mood for long periods of time (depression).
- Lack of voluntary coordination of muscle movements (ataxia).
- Tingling or numbness in your hands or feet.
- Headache.
- A change in taste.
- Cataract formation or change in your eyesight.
- Vertigo (sensation of spinning or swaying).
- High blood pressure.
- Nausea (feeling sick), vomiting (being sick), stomach pain, diarrhoea, inflamed and sore mouth, a change in your bowel habits, presence of fat in your stool.
- Abnormal liver function results when blood tests are done.
- Hair loss or discoloured hair.
- Joint pain.
- Increased urea and creatinine levels in your blood when blood tests are done.



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- Male infertility, impotence (inability to have or maintain an erection), breast enlargement in men.
- Feeling unwell or general feeling of weakness.
- Fever or chills.
- Fever, severe chills, sore throat or mouth ulcers.
- Unexplained bleeding or bruising more easily than normal.
- Feeling unable to move muscles (paralysis) or loss of consciousness.
- Fits (seizures).
- Chest pain (angina).
- Changes in the way your heart beats (beating faster or slower than normal).
- Vomiting blood.
- Yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Cancer that begins in white blood cells called T cells (angioimmunoblastic T-cell lymphoma).
- Blood in your urine.

Unknown frequency:

- Spontaneous orgasm during sleep.
- Aseptic meningitis (inflammation of the membranes that surround your brain and spinal cord, causing symptoms such as neck stiffness, headache, nausea, fever).



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If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via

<http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **REDURIC**.

5. How to store REDURIC

- Store at or below 30 °C.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton/blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage system (e.g. toilets).

6. Contents of the pack and other information

What **REDURIC** contains:

The active substance in **REDURIC** is Allopurinol.

REDURIC 100: Each tablet contains 100 mg allopurinol.

REDURIC 300: Each tablet contains 300 mg allopurinol.

The other ingredients are:

Colloidal silicon dioxide, crospovidone, FD&C Yellow no.6-aluminium lake (LAKE PIGMENT), isopropyl alcohol, lactose monohydrate, magnesium stearate, povidone PVP K30 (KOLLIDON 30) and pregelatinized starch.



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REDURIC contains sugar:

REDURIC 100: Lactose monohydrate 30,53 mg

REDURIC 300: Lactose monohydrate 90,10 mg

What REDURIC looks like and contents of the pack

REDURIC 100: White to off white coloured, flat faced beveled edged, round tablet debossed with "0" and "21" on either side of breakline and "100" on the other side.

REDURIC 300: Peach coloured, flat faced beveled edged, round tablet debossed with "300" and "020" on either side of breakline and plain on other side.

REDURIC 100 mg

Forming film: Rigid PVC Film-180mm (PVC 250 micron, clear)

Lidding foil: 25 Micron Plain Alu Foil-176mm (6-8 GSM VMCH coating)

Pack Style: (10 blister strips to be packed into a carton as per required pack size)

Pack sizes: 30's, 60's, 100's and 1000's.

REDURIC 300 mg

Forming film: Rigid PVC Film-112mm (PVC 250 micron, clear –C1)

Lidding foil: Alumlid-106mm (25 micron Alu/7GSM HSL Lidding foil)

Pack Style: (10 blister strips to be packed into a carton as per required pack size)

Pack sizes: 30's, 60's, 100's and 1000's.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Innovata Pharmaceuticals (Pty) LTD

Crownwood Office Park

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South Africa

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REDURIC 100 - 59/3.3/0111

REDURIC 300 - 59/3.3/0112

Access to the corresponding Professional information.

Is contained in the packaging or follow the link for the corresponding Professional Information for Reduric:

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below

