

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-alumium 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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100 Northern Parkway

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South Africa

This leaflet was last revised in:

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REDURIC 100 - 59/3.3/0111

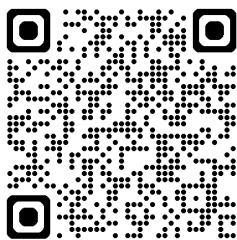
REDURIC 300 - 59/3.3/0112

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



SKEDULERINGSSTATUS: S3

REDURIC 100

Allopurinol 100 mg tablette

REDURIC 300

Allopurinol 300 mg tablette

Bevat suiker

REDURIC 100: Laktose monohidraat 30,53 mg

REDURIC 300: Laktose monohidraat 90,10 mg

Lees die volledige biljet noukeurig deur voordat u REDURIC begin neem.

- Hou hierdie biljet. U mag dit moontlik weer wil lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgvoorsiener.
- **REDURIC** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit kan hulle kwaad aandoen, selfs indien hulle simptome dieselfde is as diè wat u het.

Wat is in hierdie biljet

1. Wat **REDURIC** is en waarvoor dit gebruik word
2. Wat u behoort te weet voordat u **REDURIC** neem
3. Hoe om **REDURIC** te neem
4. Moontlike newe-effekte
5. Hoe om **REDURIC** te bêre
6. Inhoud van die pakkie en ander inligting

1. Wat REDURIC is en waarvoor dit gebruik word

REDURIC bevat 'n medisyne wat genoem word allopurinol. Dit werk deur afname in die spoed van sekere chemiese reaksies in u liggaam om die vlak van uriensuur in u bloed en uriene te laat afneem.

REDURIC word gebruik vir die afname of voorkoming van vorming van uraat/uriensuur neerslag in toestande waar u liggaam te veel van 'n substans maak wat genoem word uriensuur. Dit kan insluit jig of sommige tipes van nierstene, of sekere ander tipes van nierprobleme, of wanneer u behandeling kry vir kanker of sommige ander toestande. Met jig bou die uriensuur op in u gewrigte en senings as kristalle. Hierdie kristalle veroorsaak 'n inflammatoriese reaksie. Die inflammasie veroorsaak dat die vel rondom sekere gewrigte kan opswel, teer word en seer, selfs met slegs 'n effense aanraking. U kan ook vind dat u ernstige pyn kry wanneer u die gewrig beweeg.

2. Wat u behoort te weet voordat u REDURIC neem

Moenie REDURIC neem:

- Indien u hipersensitief (allergies) is vir allopurinol of enige van die ander bestanddele van **REDURIC** (sien Wat **REDURIC** bevat). Indien u 'n ernstige nier- of lewerprobleem het.
- Indien u tans 'n akute jigaanval het.
- Kinders, behalwe die gediagnoseer met 'n sekere tipe van kanker.
- Indien u swanger is of u baba borsvoed (sien Swangerskap, borsvoeding en fertiliteit).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met REDURIC



3. Wat u behoort te weet voordat u REDURIC neem

Moenie REDURIC neem:

- Indien u hipersensitief (allergies) is vir allopurinol of enige van die ander bestanddele van **REDURIC** nie (sien wat **REDURIC** bevat). Indien u 'n ernstige nier- of lewerprobleem het.
- Indien u op die oomblik 'n akute jigaanval het.
- Kinders, behalwe dié gediagnoseer met 'n sekere tipe van kanker.
- Indien u swanger is of u baba borsvoed (sien Swangerskap, borsvoeding en fertiliteit).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met REDURIC

- **REDURIC** behandeling moet onmiddellik gestaak word indien enige veluitslag of allergiese reaksie voorkom. Kontak u dokter vir advies indien u 'n veluitslag kry sodra die behandeling met **REDURIC** begin word.
- Indien u 'n lewer- of niersiekte het.
- Indien u hoë bloeddruk of 'n hartafwyking het en medisyne neem vir behandeling van hierdie toestande, soos diuretiese middels of AOK-remmers.
- **REDURIC** moet nie gebruik word vir die behandeling van 'n akute aanval van jig nie. **REDURIC** kan 'n akute aanval veroorsaak wanneer behandeling aanvanklik begin word. U dokter kan addisionele medisyne voorskryf gedurende die eerste maand van **REDURIC** behandeling.
- Indien u kanker het of Lesch-Nyhan se sindroom kan die hoeveelheid uriensuur toeneem in u uriene. Om dit te voorkom, moet u seker maak dat u voldoende vloeistowwe te drink om die uriene te verdun.
- Indien u nierstene het, sal die nierstene kleiner word en kan deurgaans in u urienweg.
- Indien u tiroïed-probleme het.

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Ander medisynes en REDURIC:

Vertel altyd vir u gesondheidsorgpersoon indien u enige ander medisyne neem. (Dit sluit in alle komplementêre of tradisionele medisynes.)

Vertel u dokter of apteker indien u tans die volgende gebruik:

- Vidarabien (word gebruik vir die behandeling van herpes of waterpokkies).
- Medisynes wat gebruik word by die behandeling van sekere tipes kanker, soos merkaptopurien, asatioprien en ander anti-neoplastiese medisynes.
- Medisynes wat die uriensuurkonsentrasie kan laat toeneem, soos aspirien of ander salisilate (word gebruik vir pyn en inflammasie).
- Chloorpropamied (word gebruik vir behandeling van diabetes).
- Medisynes wat gebruik word om u bloed dun te maak (antikoagulante), soos warfarien.
- Fenitoïen (word gebruik vir behandeling van epilepsie).
- Teofillien (word gebruik vir asemhaling probleme).



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- Ampisillien of amoksisillien (antibiotika wat gebruik word by die behandeling van bakteriële infeksies).
- Siklosporien (word gebruik om orgaanverwerping te voorkom na oorplanting).
- Didanosien (word gebruik om MIV/VIGS te behandel).
- Medisynes vir hartproblemes of hoë bloeddruk soos AOE-remmers of water-tablette (diuretiese middels).
- Teensuurmiddels (word gebruik by die behandeling van sooibrand of slegte spysvertering).
- Aluminiumhidroksied en **REDURIC** moet nie saam geneem word nie. Daar moet 'n tydperk van ten minste 3 uur tussenin wees wanneer albei medisynes geneem word.

REDURIC met voedsel, drankies en alkohol

Sien afdeling 3.

Swangerskap, borsvoeding en fertiliteit

Indien u swanger is of borsvoed, dink dat u swanger kan wees of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat u **REDURIC** neem.

Moenie **REDURIC** neem gedurende swangerskap of borsvoeding nie (sien afdeling 2).

Bestuur en gebruik van masjinerie

REDURIC kan newe-effekte veroorsaak, soos veranderinge in sig, lomerigheid, duiseligheid en koördinasie probleme en kan inmeng met u vermoë om 'n voertuig te bestuur of masjinerie te hanteer. Indien dit gebeur met u, moenie aan aktiwiteite deelneem waar verwag word dat u wakker moet wees nie, byvoorbeeld bestuur van 'n voertuig en gebruik van masjinerie.

Dit is nie altyd moontlik om te voorspel tot watter mate **REDURIC** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet seker maak dat hulle nie deelneem aan die boonste aktiwiteit nie, totdat hulle weet tot watter mate **REDURIC** hulle beïnvloed.

REDURIC bevat laktose monohidraat:

Indien u deur u dokter ingelig is dat u 'n intoleransie het vir sekere suikers, kontak u dokter voordat u hierdie medisyne neem.

4. Hoe om REDURIC te neem

Moenie medisyne wat vir u voorgeskryf is deel met enige ander persoon nie.

Neem altyd **REDURIC** presies soos voorgeskryf in hierdie biljet of soos u dokter of apteker aanbeveel het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Volwassenes:

Jig: Die gewone dosering is 50 mg twee keer per dag, en verhoog dan die dosis soos benodig tot 200 mg tot 400 mg per dag, in verdeelde doserings. U dokter sal besluit omtrent die regte dosering, afhangende van u liggaam se respons.

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Hyperurisemie geassosieer met leukemie: Die aanvanklike dosis is 200 mg drie keer per dag en begin, indien moontlik, 2 of 3 dae voor radioterapie. Die gewone instandhoudingsdosis is 300 mg tot 400 mg per dag.

Kinders:

U dokter sal die dosis bepaal gebaseer op die gewig van u kind.

U moet voldoende hoeveelhede vloeistof neem (ten minste 2 liters) gedurende die dag terwyl u op behandeling met **REDURIC** is.

REDURIC kan met of sonder voedsel geneem word.

U dokter sal u inlig hoe lank u behandeling met **REDURIC** sal aanhou. Indien u die indruk het dat die effek van **REDURIC** te sterk of te swak is, vertel u dokter of apteker.

Indien u meer REDURIC geneem het as wat u moes

Ingeval van oordosering, raadpleeg u dokter of apteker. Indien albei nie beskikbaar is nie, kontak die naaste hospitaal of vergiftingsentrum.

Neem hierdie biljet en die res van die oorblywende **REDURIC** saam met u sodat die dokter sal weet wat u geneem het.

Indien u vergeet met om REDURIC te neem

Indien u 'n dosis gemis het met slegs 'n paar ure, neem die dosis wat u oorgeslaan het so gou as wat u onthou. Indien dit amper tyd is vir u volgende dosis, slaan die dosis oor wat u gemis het en neem **REDURIC** op die volgende gewone geskudeleerde tyd.



Moenie 'n dubbel dosis neem om op te maak vir die individuele doserings wat u vergeet het nie.

5. Moontlike newe-effekte

REDURIC kan newe effekte hê. Nie alle newe-effekte gerapporteer vir **REDURIC** is ingesluit in hierdie biljet nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ondervind terwyl u **REDURIC** neem, raadpleeg asseblief u gesondheidsorgvoorsiener vir advies. Indien enige van die volgende gebeur, staak die gebruik van **REDURIC** en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal:

- opswel van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak met sluk of asemhaling;
- uitslag of jeuk;
- floute.

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, het u moontlik 'n ernstige reaksie gehad met **REDURIC**. U kan dringende mediese aandag benodig of hospitalisering.

Vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

Dikwelse newe-effekte:

- Uitslag
- Verhoogde tiroïedvlakke wanneer bloedtoetse gedoen word.

Minder dikwelse newe-effekte:

- Bloedvinte (rooi, opgeswelde knop op u vel veroorsaak deur infeksie rondom die haar-follikels).
- Anemie (moegheid, verlies aan energie, bleek vel, krampe in u bene, probleme met konsentrasie).
- Vaskulitis (inflammasie van u bloedvate, wat koors, hoofpyn, moegheid, massaverlies, algemene seer en pyne, nagsweet, senuweeprobleme soos gevoelloosheid of swakheid kan veroorsaak.
- Hoë bloedsuikervlakke (diabetes).
- Hoë vlakke van cholesterol in u bloed (hiperlipidemie).
- Lomerigheid of slaperigheid.
- Bedroef voel vir lang tye (depressie).
- Gebrek aan willekeurige koördinasie van spierbewegings (ataksie).
- Tinteling of gevoelloosheid in u hande of voete.
- Hoofpyn.
- 'n Verandering in smaak.
- Katarakvorming of verandering in u sig (hoe u sien).
- Vertigo (sensasie van draai of swaai).
- Hoë bloeddruk.
- Naarheid (gevoel van siek wees), braking (siek wees), maagpyn, diarree, ontsteekte en seer mond, 'n verandering in u ingewande se gewoontes, voorkoms van vet in u stoelgang.
- Abnormale lewerfunksie resultate wanneer bloedtoetse gedoen word.
- Haarverlies of verkleurde hare.
- Gewrigspyn.
- Verhoogde ureum- en kreatinienvlakke in u bloed wanneer bloedtoetse gedoen word.

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*

Product Proprietary Name: *REDURIC 100 & 300*

Dosage Form & Strength: *Tablets, (Allopurinol 100 mg & Allopurinol 300 mg)*

- Manlike onvrugbaarheid, impotensie (onvermoë om 'n ereksie te kry of te behou), borsvergroting in mans.
- Gevoel van siek wees of algemene gevoel van swakheid.
- Koors, erge koue gevoel, seerkeel of mondsere.
- Onverklaarbare bloeding of u kneus makliker as gewoonlik.
- Gevoel van onvermoë om spiere te beweeg (paralise) of verlies van bewussyn.
- Stuipe (siekte-aanvalle).
- Borspyn (angina).
- Veranderinge van die manier waarop u hart klop (klop vinniger of stadiger as gewoonlik).
- Braking van bloed.
- Geel word van u vel en oë, donker uriene en moegheid, wat simptome kan wees van lewerprobleme.
- Pynlike, blasievorming of afdop, soos Stevens-Johnson se sindroom of toksiese epidermale nekrolise.
- Kanker wat begin in wit bloedselle en genoem word T-selle (angio-immunoblastiese T-sel limfoom).
- Bloed in u uriene.

Onbekende frekwensie:

- Spontane orgasme gedurende slaap.
- Aseptiese meningitis (inflammasie van die membrane wat u brein en rugstring omring, wat simptome veroorsaak soos 'n stywe nek, hoofpyn, naarheid, koors).



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Indien u enige newe-effekte opmerk wat nie gemeld word in hierdie biljet nie, laat weet u dokter of apteker daarvan.

Rapporteur van newe-effekte

Indien u newe-effekte kry, raadpleeg u dokter, apteker of verpleegkundige.

Dit sluit in enige moontlike newe-effekte nie aangedui in hierdie biljet nie.

U kan newe-effekte ook rapporteer via <http://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte te rapporteer kan u help om meer inligting te voorsien omtrent die veiligheid van **REDURIC**.

6. Hoe om REDURIC te berg

- Berg by of benede 30 °C.
- Hou in die oorspronklike houer totdat dit benodig word vir gebruik.
- Berg alle medisyne buite die bereik van kinders.
- Moenie gebruik na die vervaldatum wat gedruk is op die karton/stolp nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ontslae raak van ongebruikte medisyne deur dit in afvoerpype en rioolstelsels te gooi nie (bv. toilette).

7. Inhoud van die pakkie en ander inligting

Wat **REDURIC** bevat:

Die aktiewe substans in **REDURIC** is Allopurinol.

REDURIC 100: Elke tablet bevat 100 mg allopurinol.

REDURIC 300: Elke tablet bevat 300 mg allopurinol.

Die ander bestanddele is:

Kolloïdale silikoondioksied, krosprovidoon, FD&C Geel nr. 6-alumium lake (LAKE PIGMENT), isopropiel alkohol, laktose monohidraat, magnesiumstearaat, providoon PVP K30 (KOLLIDON 30) en gepregelatiniseerde stysel.



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Product Proprietary Name: REDURIC 100 & 300
Dosage Form & Strength: Tablets, (Allopurinol 100 mg & Allopurinol 300 mg)

REDURIC bevat suiker:

REDURIC 100: Laktose monohidraat 30,53 mg

REDURIC 300: Laktose monohidraat 90,10 mg

Hoe REDURIC lyk en inhoud van die pakkie

REDURIC 100: Wit tot naaswit kleur, plat voorkoms skuinskantige, ronde tablet gebosseleer met "0" en "21" op een van beide kante van breeklyn en "100" op die ander kant.

REDURIC 300: Perske kleurige, plat voorkoms skuinskantige, ronde tablet gebosseleer met "300" en "020" op een van beide kante van breeklyn en glad op die ander kant.

REDURIC 100 mg

Vorm-foelie: Rigiede PVC Film-180 mm (PVC 250 mikron, helder)

Dek-foelie: 25 Mikron Plat Alu Foelie-176 mm (6-8 GSM VMCH bedekking)

Pakstyl: (10 stolpstrookies word verpak in 'n karton soos benodig vir pakgrootte)

Pakgroottes: 30's, 60's, 100's en 1000's.

REDURIC 300 mg

Vorm-foelie: Rigiede PVC Film-112 mm (PVC 250 mikron, helder –C1)

Dek-foelie: Alumlid-106 mm (25 mikron Alu/7GSM HSL Dekfoelie)

Pakstyl: (10 stolpstrookies word verpak in 'n karton soos benodig vir pakgrootte)

Pakgroottes: 30's, 60's, 100's en 1000's.

NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE

SERTIFIKAAT VAN REGISTRASIE

Innovata Pharmaceuticals (Pty) LTD

Crownwood Office Park

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

100 Northern Parkway

Ormonde Johannesburg

2091

Suid-Afrika

Hierdie biljet was laas hersien in:

New-11/03/2025

Registrasiennommers:

REDURIC 100 - 59/3.3/0111

REDURIC 300 - 59/3.3/0112

Toegang tot die ooreenstemmende Professionele Inligting.

Ingesluit in die verpakking of volg die skakel vir die ooreenstemmende Professionele Inligting vir

REDURIC:

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

alternatief skandeer asseblief die QR-kode hieronder:

