PATIENT INFORMATION LEAFLET

Information for the Patient about

ALLOPURINOL UNICORN

SCHEDULING STATUS:

Schedule 3

ALLOPURINOL 100 UNICORN (100 mg allopurinol) tablets

ALLOPURINOL 300 UNICORN (300 mg allopurinol) tablets

Contains sugar: lactose monohydrate.

Read all of this leaflet carefully before you start taking ALLOPURINOL UNICORN

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

ALLOPURINOL UNICORN 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 ALLOPURINOL UNICORN is and what it is used for

2. What you need to know before you take ALLOPURINOL UNICORN

3. How to take ALLOPURINOL UNICORN

4. Possible side effects

5. How to store ALLOPURINOL UNICORN

6. Contents of the pack and other information

1. What ALLOPURINOL UNICORN is and what it is used for

ALLOPURINOL UNICORN contains allopurinol, an anti-gout medicine. Allopurinol decreases the levels of uric acid in your body.

ALLOPURINOL UNICORN is used for the treatment of:

- Gout
- Conditions associated with high blood uric acid levels including kidney disease, radiation therapy used for cancer treatment, cancer (such as leukaemia) and treatment with diuretics (water tablets) and anti-cancer medicines (such as mercaptopurine).

2. What you need to know before you take ALLOPURINOL UNICORN

Do NOT take ALLOPURINOL UNICORN:

- If you are hypersensitive (allergic) to allopurinol or any of the other ingredients of **ALLOPURINOL UNICORN.**
- If you have been diagnosed with an acute attack of gout.
- In children, unless diagnosed with a type of cancer.
- If you are a mother breastfeeding your baby**.**

Warnings and precautions:

Take special care with ALLOPURINOL UNICORN

- If you develop serious skin rashes. Discontinue the use of **ALLOPURINOL UNICORN**

immediately and consult your doctor. These skin reactions include hypersensitivity reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis (which may be life-threatening), especially if they are accompanied by blisters, fever, peeling of the skin, joint pain, swollen glands (throat and/or under arms). These skin rashes are more common in patients with chronic renal impairment and in people of Asian descendants.

- If you have liver or kidney damage, your doctor will need to reduce the dose of **ALLOPURINOL UNICORN.**
- If you have a thyroid problem and you are taking **ALLOPURINOL UNICORN** long term, this medicine may increase your blood levels of thyroid stimulating hormone (TSH).
- If you are diagnosed with high levels of uric acid in the blood, but you are not experiencing any symptoms of gout (painful and swollen joints), your doctor may adjust your diet and advise that you increase your water intake, before starting therapy with **ALLOPURINOL UNICORN**.
- **ALLOPURINOL UNICORN** should not be started until the gout attack has cleared, because allopurinol may worsen this condition.
- If you have a condition that may increase the levels of urate in the body (for example Lesch-Nyhan syndrome), this may lead to the formation of crystals in the urinary tract. It is advised that you increase your water intake, to prevent the crystal formation when using **ALLOPURINOL UNICORN**.
- If you have high levels of uric acid in the blood, you may be at risk of kidney stones (uric acid crystals forming in the tubes, which lead from the kidneys to the bladder). Therapy with **ALLOPURINOL UNICORN** will dissolve large crystals, which will lead to blockage of the tubes.

Children

ALLOPURINOL UNICORN should not be used in children, unless advised by a specialist.

Other medicines and ALLOPURINOL UNICORN

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please discuss the use of the following medicines or substances in combination with **ALLOPURINOL UNICORN** with your doctor or pharmacist:

- Immuno-suppressants (medicines used to reduce your immune response), such as azathioprine, ciclosporin (*also cyclosporin*) and 6-mercaptopurine
- Vidarabine, an anti-viral medicine used to treat herpes infections
- Didanosine, a medicine used to treat HIV infection
- Other medicine to treat gout, such as aspirin, benzbromarone and probenecid
- Medicines used to thin your blood (anticoagulants), such as warfarin
- Medicines used to treat diabetes, such as chlorpropamide
- Medicines for heart problems or high blood pressure such as ACE inhibitors (such as enalapril) or water tablets (diuretics)
- Medicines used to treat heartburn such as aluminium hydroxide. You should wait at least 3 hours between taking these 2 medicines
- Medicines used to treat epilepsy (fits), such as phenytoin
- Theophylline, a medicine used to treat breathing problems

- Antibiotics, such as ampicillin and amoxicillin
- Medicines for cancer, such as bleomycin, cyclophosphamide, doxorubicin, mechloroethamine, procarbazine.

ALLOPURINOL UNICORN with food and drink:

ALLOPURINOL UNICORN can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

The safety and efficacy of **ALLOPURINOL UNICORN** during pregnancy and breastfeeding have not been established, therefore you should not use **ALLOPURINOL UNICORN** if you are pregnant or breastfeeding your baby.

Driving or using machinery:

ALLOPURINOL UNICORN frequently causes the following side effects, drowsiness, dizziness and disturbances in your eyesight**.** Therefore, you should not drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether **ALLOPURINOL UNICORN** affects your ability to perform such tasks.

ALLOPURINOL UNICORN contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ALLOPURINOL UNICORN.**

3. HOW TO TAKE ALLOPURINOL UNICORN:

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

Always take **ALLOPURINOL UNICORN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Oral

Adults:

Gout:

The usual starting dose of **ALLOPURINOL UNICORN** is 50 mg twice a day. Your doctor may increase your dose to 200 – 400 mg a day, in divided doses.

High uric acid levels associated with cancer (such as leukemia):

Your doctor will start treatment with **ALLOPURINOL UNICORN** before you start chemotherapy, or together with your anti-cancer medicines.

The usual starting dose of **ALLOPURINOL UNICORN** is 200 mg three times a day.

Your doctor will increase your dose to 300 – 400 mg a day, in divided doses.

Children

The dosage for children is calculated based on the child's bodyweight.

If you have a serious kidney problem:

Your doctor will prescribe a reduced dosage, based on your kidney function.

Do not exceed the recommended daily dosage.

If you take more ALLOPURINOL UNICORN than you should:

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

Signs and symptoms of overdosage may include abdominal pain, diarrhoea, dizziness, headache, nausea (feeling sick), vomiting and feeling tired. Tell your doctor if you use more **ALLOPURINOL UNICORN** than you should.

If you forget to take ALLOPURINOL UNICORN

Always take **ALLOPURINOL UNICORN** as prescribed (see **"HOW TO TAKE ALLOPURINOL UNICORN"**). If you have missed a dose, take it as soon as you remember. Do not take a double dose of **ALLOPURINOL UNICORN** to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

ALLOPURINOL UNICORN can have side effects.

Not all side-effects reported for **ALLOPURINOL UNICORN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ALLOPURINOL UNICORN** 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
- fever and/or chills
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to **ALLOPURINOL UNICORN**. 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:

- angina
- changes in the way your heart beats, for example, if you notice it beating slower
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

The following side effects are frequently associated with **ALLOPURINOL UNICORN:**

- Rash
- An increase in your hormone known as thyroid stimulating hormone.

The following side effects are less frequently associated with **ALLOPURINOL UNICORN:**

- Boils
- Decreased levels of blood components such as white blood cells, red blood cells

and platelets

- Allergic reactions, including skin rash, boils or sore lips and mouth, fever, chills and joint pain
- Diabetes mellitus (Signs and symptoms of this condition includes feeling thirsty, tired and losing weight) and high levels of cholesterol in your blood (hyperlipidaemia)
- Feeling depressed (sad)
- Loss of control of muscle movements, loss of consciousness, headache, tingling feeling (“pins and needles”), paralysis (unable to move limbs/muscles), feeling tired (drowsy), a change in taste
- Cataracts (clouding of the lens of the eye), loss of vision and disturbance in vision
- Vertigo (a feeling of dizziness or “spinning”)
- Angina (chest pain) and irregular slow heartbeat
- High blood pressure
- Change in normal bowel movement, vomiting of blood, abnormal amount of fat in faeces, inflamed or sore mouth, and nausea and vomiting
- Increase in liver test results and inflammation of the liver
- Hair loss, swelling of the face, discoloured hair, serious skin reaction including boils, blisters, itching, swelling and fever
- Abnormally high levels of nitrogen-containing compounds (such as urea, creatinine, various body waste compounds, and other nitrogen-rich compounds) in the blood and urine; and blood present in the urine
- Enlargement of the breasts (in males and females), male infertility or erectile dysfunction
- Feeling weak or lack of energy, fever, feeling tired, build-up of fluid leading to

swelling (oedema) particularly of your ankles.

The following side effects frequency is unknown:

- Increase and decrease in white blood cells, abnormal breakdown of red blood cells causing you to feel tired and weak
- Pain in the joints
- Worsening of gout
- Dizziness and drowsiness
- Inflammation of blood vessels causing a rash
- Abdominal pain, diarrhoea and irritation of the stomach
- Skin reactions including hives (skin rash with raised, itchy bumps) and blisters
- Formation of kidney stones
- Experiencing a spontaneous orgasm during sleep (“wet dream”).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety of **ALLOPURINOL UNICORN**.

5. How to store ALLOPURINOL UNICORN

Store at or below 25 ºC.

Protect from light.

Store in the original packaging.

Do not take after the expiry date stated on the package.

Return all unused **ALLOPURINOL UNICORN** to your pharmacist.

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

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ALLOPURINOL UNICORN contains

The active substance is allopurinol.

The other ingredients are: Maize starch, povidone, sodium starch glycollate, stearic acid, sunset yellow.

Contains sugar: lactose monohydrate.

What ALLOPURINOL UNICORN looks like and contents of the pack

ALLOPURINOL 100 UNICORN: white to off-white, approximately 7,5 mm round, biconvex, uncoated tablets with ‘AL’ & ‘100” separated by breakline on one side & plain on other side.

ALLOPURINOL 300 UNICORN: Peach coloured, approximately 11 mm round, biconvex, uncoated tablets with ‘AL’ & ‘300’ separated by breakline on one side and plain on other side.

ALLOPURINOL 100 UNICORN tablets are packed in clear PVDC coated PVC/Aluminium blister strips of 10 tablets, 10 blister strips are further packed in an outer carton. Pack size: 100 tablets.

ALLOPURINOL 300 UNICORN tablets are packed in clear PVDC coated PVC/Aluminium blister strips of 10 tablets, 3 blister strips are further packed in an outer carton. Pack size: 30 tablets.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

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Cape Town

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Registration numbers

ALLOPURINOL 100 UNICORN: 54/3.3/0583

ALLOPURINOL 300 UNICORN: 54/3.3/0584

This leaflet was last revised in: Not applicable