Approved Patient Information Leaflet for Medicines for Human Use:

[PRODUCT NAME]

SCHEDULING STATUS: S3

[PRODUCT NAME] 100, 100 mg tablets

Allopurinol

Contains sugar: lactose monohydrate 52,03 mg

[PRODUCT NAME] 300, 300 mg tablets

Allopurinol

Contains sugar: lactose monohydrate 153,60 mg

Read all of this leaflet carefully before you start taking [PRODUCT NAME]

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or pharmacist, nurse or other health care provider.
- [PRODUCT NAME] 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 [PRODUCT NAME] is and what it is used for

2. What you need to know before you take [PRODUCT NAME]

3. How to take [PRODUCT NAME]

4. Possible side effects

5. How to store [PRODUCT NAME]

6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

Your medication is called [PRODUCT NAME]. It contains a medicine called allopurinol.

Each [PRODUCT NAME] 100 tablet contains 100 mg allopurinol.

Each [PRODUCT NAME] 300 tablet contains 300 mg allopurinol.

Allopurinol works by slowing down the speed of certain chemical reactions in your body.

[PRODUCT NAME] is used:

- to prevent gout: this is a disease in which your body produces too much of a substance called uric acid. Allopurinol works by decreasing the amount of uric acid produced in your body.
- to prevent other conditions where there is an increased amount of uric acid formed in the body such as in leukaemia (a type of cancer), during radiotherapy treatment (a treatment for cancer) and treatment with certain medications such as mercaptopurine (a treatment for cancer and some immune diseases) or diuretics ("water tablets").

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME]:

- if you are hypersensitive (allergic) to allopurinol or any of the other ingredients of [PRODUCT NAME] (listed in section 6)
- if you are pregnant or breastfeeding your baby
- [PRODUCT NAME] should not be given to children, unless they have cancer

Warnings and precautions

Take special care with [PRODUCT NAME]**:**

- if you have a kidney problem as your doctor may reduce your dose of [PRODUCT NAME]

- if you are currently having an attack of gout
- if you are taking a medication called azathioprine or mercaptopurine (these are medications used after organ transplantation and for the treatment of cancer and some immune diseases)
- if you have a liver or kidney problem
- whilst taking [PRODUCT NAME], ensure that you drink sufficient amounts of water, your doctor will advise you on how much water you should drink daily
- serious skin rashes (hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) can occur whilst taking [PRODUCT NAME]. Before these rashes develop, you may have “flu-like” symptoms such as fever (high temperature), headache, and body ache. The rash may progress to blistering and peeling of the skin of the entire body. If you develop a rash or these skin symptoms while taking [PRODUCT NAME], stop taking [PRODUCT NAME] and contact your doctor immediately
- if you have problems with your thyroid

Children

Children with Lesch-Nyhan syndrome, a type of juvenile gout, may develop kidney stones. This can be minimised by increasing daily fluid intake and alkalinisation of the urine. Your doctor will advise you on what to give to your child.

Other medicines and [PRODUCT NAME]

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

Tell your doctor if you are taking any medicines containing the following:

- aluminium hydroxide (used to treat heartburn or acid indigestion) may increase

the effect of [PRODUCT NAME]

- mercaptopurine, ciclosporin or azathioprine (these are medications used after organ transplantation and/ or for the treatment of cancer and some immune diseases) cyclophosphamide or other treatments for cancer such as doxorubicin, bleomycin, procarbazine and mechloroethamine
- theophylline (medicine for asthma and found in some cough mixtures)
- chlorpropamide (this is a medication used to treat diabetes)
- probenecid (medicine used to treat gout) or salicylates (medicine used to treat pain)
- medicines, used to treat high blood pressure and other heart conditions, such as ACE inhibitors (e.g. captopril) and diuretics “water tablets”
- warfarin (medicine used to “thin” your blood)
- amoxicillin or ampicillin (medicines used to treat bacterial infections)
- vidarabine (medicine used to treat viral infections)
- didanosine (medicine used in the treatment of HIV)
- phenytoin (medicine used in the treatment of epilepsy “fits”).

Consult your doctor, pharmacist or other healthcare professional as these medicines may interact with [PRODUCT NAME].

[PRODUCT NAME] with food and drink

Take [PRODUCT NAME] tablets with a drink of water.

Take with or just after food.

Drink plenty of fluids while taking [PRODUCT NAME].

Pregnancy and, breastfeeding and fertility

You should not take [PRODUCT NAME] if you are pregnant or breastfeeding your baby (see “Do not take [PRODUCT NAME”).

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 [PRODUCT NAME].

Driving and using machines

[PRODUCT NAME] may cause headaches and make you feel drowsy or dizzy. If you are feeling this way, do not drive or operate machinery.

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

[PRODUCT NAME] contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking [PRODUCT NAME].

3. How to take [PRODUCT NAME]

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

Always take [PRODUCT NAME] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that [PRODUCT NAME] is too strong or too weak, tell your doctor or pharmacist.

Adults

The usual starting dose is 100 mg and this may be increased by your doctor depending on how severe your condition is.

Gout

The usual dose is 100 mg per day and to increase this dose as required to 200 mg to 400 mg in divided doses. Your doctor will decide on the correct dose, depending on your body's response.

Hyperuricaemia associated with leukaemia

The initial dose is 200 mg three times daily commencing, if possible, 2 or 3 days before radio therapy. The usual maintenance dose is 300 mg to 400 mg daily.
You should take adequate amounts of fluid (at least 2 litres) during the day while on treatment with [PRODUCT NAME]

In children under 15 years:

The dose of [PRODUCT NAME] is usually determined by weight in children.

If you have a serious kidney problem:

Your dose will be adjusted according to the results of your kidney function tests. If you are unsure as to whether your dose should be adjusted, contact your doctor or pharmacist.
Your doctor will tell you how long your treatment with [PRODUCT NAME] will last. Do not stop treatment early without discussing it with your doctor. If you have the impression that the effect of [PRODUCT NAME] is too strong or too weak, tell your doctor or pharmacist.

If you take more [PRODUCT NAME] than you should:

If you have taken too much [PRODUCT NAME] you may experience nausea, vomiting, diarrhoea and dizziness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take [PRODUCT NAME]:

Take your dose of [PRODUCT NAME] as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose.

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

If you stop taking [PRODUCT NAME]:

Do not stop taking [PRODUCT NAME] unless your doctor instructs you to stop treatment.

If you stop taking [PRODUCT NAME], your original symptoms may come back.

4. Possible side effects

[PRODUCT NAME] can have side effects.

Not all side effects reported for [PRODUCT NAME] are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking [PRODUCT NAME], please consult your health care provider for advice.

If any of the following happens, stop taking [PRODUCT NAME] and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a rash, that develops quickly, with itching and peeling or flaking of your skin and possibly blistering of the mouth and the genital and anal regions. Your eyes may also be affected and may be red and swollen
- fever (high temperature) and chills, flu-like symptoms such as pain in the joints.
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- fainting

These are very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. 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:

- high blood pressure
- angina (chest pain)
- lower than normal heart rate
- high blood sugar levels
- seizures
- blood when vomiting
- blood in the urine
- numbness and tingling in your arms or legs
- feeling unable to move your body (paralysis), having a “fit” (epilepsy), loss of consciousness
- stomach pain, nausea, unusual tiredness, dark-coloured urine, light-coloured bowel movements, loss of appetite, fever, yellowing of the skin and eyes. also called jaundice. These may be signs of liver damage

- abnormally low levels of urine, swelling of your legs, ankles or feet, unexplained shortness of breath, feeling abnormally tired, constant nausea, confusion, pain or pressure in your chest. These may be signs of kidney damage
- aseptic meningitis (inflammation of the membrane covering the brain and spinal cord)

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

Tell your doctor if you notice any of the following:

Frequent:

- any skin rash

Less frequent:

- a decrease in your white blood cells. In such a case you will notice tiredness, fever or an infection
- peripheral neuritis (a tingling or numbness usually in the tips of your fingers “pins and needles”)
- feeling drowsy or sleepy, feeling unbalanced and unable to control your movements, headache
- cataract formation or change in your ability to see
- vertigo (feeling dizzy or experiencing a spinning sensation while standing still)
- fluid build-up causing swelling of parts of the body such as the ankles and feet
- feeling in a sad mood for long periods of time (depression)
- feeling sick (nausea) and being sick (vomiting)
- enlargement of the breasts
- male infertility, impotence (being unable to have or to maintain an erection)
- hair loss, change in the colour of your hair
- joint pain

- increase in cholesterol levels (noticeable on a blood test)
- infection of the skin “boils”
- change in taste or feeling “unwell” (malaise)
- pain in the abdomen (stomach area/ “midsection”)
- gastric irritation (you will notice a burning sensation in your stomach)
- diarrhoea.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME]**.**

5. How to store [PRODUCT NAME]

Store all medicines out of reach of children

- Store in the original packaging. Keep blister packs in the carton until required for use.
- Store at or below 25 °C.
- Do not store your medicine in the bathroom.
- Do not use [PRODUCT NAME] after the expiry date printed on the label, container or blister.

- Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What [PRODUCT NAME] contains

- The active substance of:

  [PRODUCT NAME] 100 is 100 mg of allopurinol.

  [PRODUCT NAME] 300 is 300 mg of allopurinol.
- The other ingredients are dried maize starch, lactose monohydrate, maize starch, micronized stearic acid, povidone and sodium starch glycollate.

[PRODUCT NAME] 300 tablets also contain a colourant: sunset yellow FCF aluminium lake (E110).

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 100 tablets are white to off-white coloured, round, biconvex uncoated tablets with 'AL' and '100' separated by a breakline on one side and plain on the other side. Tablet diameter: approximately 7,5 mm

[PRODUCT NAME] 300 tablets are peach coloured, round, biconvex uncoated tablets with 'AL' and 300 separated by a breakline on one side and plain on the other side. Tablet diameter: approximately 11,0 mm

[PRODUCT NAME] tablets are packed in clear PVDC coated PVC/Aluminium foil blister strips of 7 or 10, which are further packed in printed cartons, in pack sizes of 28, 30 or 100 tablets. Not all pack sizes are necessarily marketed.

Not all pack sizes may be marketed.

Austell Pharmaceuticals (Pty) Ltd, 49/3.3/0016-21, Allopurinol Austell/Camox, Lessuric, Tablet and 100 mg and 300 mg

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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