

**Clean Amended Patient Information Leaflet for Medicines for Human Use:**

**URIPOLT 100 & 300 mg Tablets**

**SCHEDULING STATUS:** S3

**URIPOLT 100 mg tablets**

**URIPOLT 300 mg tablets**

**Allopurinol**

Contains sugar (lactose monohydrate): 37,26 mg per tablet

Contains sugar (lactose monohydrate): 111,80 mg per tablet.

**Read all of this leaflet carefully before you start taking URIPOLT.**

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

**1. What URIPOLT is and what it is used for**

URIPOLT 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 the blood and urine. They are used to prevent gout and other conditions associated with excess uric acid in the body, including kidney stones and certain types of kidney disease. URIPOLT should not be used to treat a sudden attack of gout.

## **2. What you need to know before you take URIPOLT**

- If you are hypersensitive (allergic) to allopurinol or any of the other ingredients of URIPOLT (listed in section 6).
- If you suffer from a severe liver or kidney disease.
- If you have sudden attacks of gout.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking URIPOLT:

- If you are of Han Chinese, African or Indian origin.
- If you have problems with your liver or kidneys. Your doctor may give you a lower dose or ask you to take it less often than each day.
- If you have heart problems or high blood pressure and you take diuretics and/or a medicine called ACE-inhibitors.
- If you are currently having an attack of gout.
- If you have thyroid problems.

Take special care with URIPOLT:

- Serious skin rashes (Hypersensitivity syndrome, Stevens- Johnson syndrome, toxic epidermal necrolysis) have been reported in patients taking allopurinol as found in URIPOLT. Frequently, the rash can involve 2 ulcers of the mouth, throat, nose, genitals and

conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. These serious skin reactions can be more common in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients additionally. If you develop a rash or these skin symptoms, stop taking URIPOLT and contact your doctor immediately.

- 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 sufficiently to dilute your urine.
- In case you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.
- Thrombocytopenia, agranulocytosis and aplastic anaemia, particularly in individuals with impaired renal and/or hepatic function have been reported, reinforcing the need for particular care in hepatic and renal group of patients.
- Associated vasculitis and tissue response may be manifested in various ways including hepatitis, renal impairment and very rarely, seizures. Acute anaphylactic shock has been reported. If such reactions do occur, it may be at any time during treatment. URIPOLT should be withdrawn immediately and permanently.

### **Other medicines and URIPOLT**

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

Tell your doctor or pharmacist if you are taking any of the following:

- aspirin
- theophylline, used for breathing problems
- medicines used for fits (epilepsy), phenytoin

- vidarabine, used to treat herpes or chickenpox
- antibiotics (ampicillin or amoxicillin)
- didanosine, used to treat HIV infection
- medicines used for cancer
- medicines used to treat your immune response (immunosuppressants) e.g. azathioprine
- medicines used to treat diabetes
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics)
- medicines used to thin your blood (anticoagulants), such as warfarin
- any other medicine to treat gout

If aluminium hydroxide is taken concomitantly, allopurinol may have an attenuated effect. There should be an interval of at least 3 hours between taking both medicines.

With administration of URIPOLT and cytostatics (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides), blood dyscrasias occur more frequently than when these active substances are administered alone.

Blood count monitoring should therefore be performed at regular intervals.

### **URIPOLT with food and drink**

URIPOLT must be taken after a meal.

### **Pregnancy, breastfeeding and infertility**

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 this medicine.

URIPOLT should not be taken if you are pregnant or breastfeeding your baby.

URIPOLT may cause infertility in male patients.

### **Driving and using machines**

URIPOLT may make you feel drowsy, dizzy or you may have problems with your coordination. If this happens, do not drive or use any tools or machines.

### **URIPOLT contains lactose**

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

URIPOLT contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

### **3. How to take URIPOLT**

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

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

#### *Adults*

The usual starting dose is in the range of 100 mg to 300 mg daily, which may be taken as a single dose, after a meal. The tablets should be taken with a little water to make swallowing easier. The dose may be increased up to 900 mg daily, depending on the severity of your condition.

#### *Children (under 15 years)*

The usual dose ranges from 100 to 400 mg each day.

#### Reduced liver or kidney function

If you have reduced liver or kidney function, your doctor may prescribe a lower dose or to take it at longer intervals. If you have dialysis two or three times a week, your doctor may prescribe a dose of 300 or 400 mg which is to be taken straight after your dialysis.

Your doctor will tell you how long your treatment with URIPOLT will last.

If you have the impression that the effect of URIPOLT is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more URIPOLT than you should**

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

Signs of an overdose may include nausea, vomiting, diarrhoea and dizziness.

#### **If you forget to take URIPOLT**

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

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

#### **If you stop taking URIPOLT**

Do not stop taking URIPOLT without talking to your doctor first.

#### **4. Possible side effects**

URIPOLT can have side effects.

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

If any of the following happens, stop taking URIPOLT 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 URIPOLT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequent*

- skin rash
- increased level of thyroid stimulating hormone in the blood when blood tests are done.

*Less frequent*

- feeling sick (nausea) or being sick (vomiting)
- abnormal liver tests when blood tests are done.
- liver problems such as liver inflammation e.g. yellowing of your skin and eyes.
- boils (red, raised bumps on your skin caused by a bacterial infection)
- URIPOLT may affect your blood, which can manifest as bruising more easily than usual, or you may develop a sore throat or other signs of an infection (these effects usually occur in people with liver or kidney problems)

- may affect the lymph nodes
- high temperature
- blood in your urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell or feeling weak
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, dizziness, drowsiness or disturbance of your vision
- chest pain (angina), high blood pressure or a slow pulse
- joint pain (arthralgia)
- inflammation of the area of the kidney known as the renal interstitium (interstitial nephritis)
- kidney damage
- male infertility or erectile dysfunction
- enlargement of the breasts, in men as well as women
- a change in your normal bowel habit
- a change in taste perception
- cataracts (clouding of the normally clear lens of the eye)
- hair loss or discolouration
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- buildup of fluid leading to swelling (oedema) particularly of your ankles
- abnormal glucose metabolism (diabetes)
- high levels of urea in the blood
- cancer that begins in white blood cells called T cells (angioimmunoblastic T-cell lymphoma).
- swollen lymph nodes

- 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).
- chills

*Side effects with frequency unknown:*

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

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of URIPOLT.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via [medsafety@austell.co.za](mailto:medsafety@austell.co.za)

### **5. How to store URIPOLT**

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original package to protect from moisture and light.
- Do not use after the expiry date stated on the blister / carton.

Return all unused medicine to your pharmacist.

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

## **6. Contents of the pack and other information**

### **What URIPOLT contains**

- The active ingredient is allopurinol.
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch and povidone.

### **What URIPOLT looks like and contents of the pack**

URIPOLT 100 tablets are white to off white, scored, flat cylindrical tablets debossed with 'I' and '56' on either side of the break line on one side and plain on the other side.

URIPOLT 300 tablets are white to off white, scored, flat cylindrical tablets debossed with 'I' and '57' on either side of the break line on one side and plain on the other side.

URIPOLT 100 and URIPOLT 300 are packed in clear PVC/Aluminium blister strips.

The blisters are packed in cartons which are finally packed inside shippers.

Pack size: Blister strips are packed in 2 x 14's or 4 x 14's.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

Ascendis Pharma (Pty) Ltd  
31 Georgian Crescent East  
Bryanston  
2191  
South Africa

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**Registration numbers**

URIPOLT 100 – 56/3.3/0893

URIPOLT 300 – 56/3.3/0894

**Access to the corresponding Professional Information**

To be confirmed.