

1.3.2.1 APPROVED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LOPRICID 100 tablets

Contains sugar: Lactose monohydrate 30,53 mg per tablet.

LOPRICID 300 tablets

Contains sugar: Lactose monohydrate 90,10 mg per tablet.

Allopurinol

Read all of this leaflet carefully before you start taking LOPRICID

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

1. What LOPRICID is and what it is used for

LOPRICID contains the active substance allopurinol. It works by slowing down the speed of certain chemical reactions in your body.

LOPRICID is used to:

- treat gout. This is a disease where your body produces too much of a substance called uric acid. 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 touched. Severe pain is also experienced when the joint is moved.
- treat other conditions where there is a build-up of uric acid in the body. These include kidney stones and certain other types of kidney problems and when you are having treatment for cancer.

2. What you need to know before you take LOPRICID

Do not take LOPRICID:

- If you are hypersensitive (allergic) to allopurinol or any of the other ingredients of LOPRICID (listed in section 6).
- If you are pregnant or breastfeeding your baby.

LOPRICID is not recommended in children, except those with abnormal cell growth (malignancy).

Warnings and precautions

Take special care LOPRICID:

- If you develop any skin rash or allergic reaction. LOPRICID should be stopped and contact your doctor for advice if you develop a skin rash once starting treatment with LOPRICID.
- If you develop angioedema (swelling of the face, lips, tongue, or throat), with or without other allergy symptoms, seek medical help immediately.
- If you have a gene called HLA-B*5801, you may be at higher risk of a serious skin reaction to allopurinol.
- If you have a liver or kidney disorder. You may be at higher risk of rare blood disorders, diagnosed by blood tests, such as:
 - Thrombocytopenia (low platelets)

- Agranulocytosis (low white blood cells)
- Aplastic anaemia (a condition where the body does not make enough blood cells)
- 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.
- LOPRICID should not be used to treat an acute attack of gout. LOPRICID may cause an acute attack when starting treatment initially. Your doctor may prescribe additional medicines during the first month of LOPRICID treatment.
- In Lesch-Nyhan syndrome. Increasing the daily fluid intake and taking urinary alkalinisers can reduce the side effects.
- If you suffer from any urinary disorders. Consult your doctor for advice.
- If you suffer from any thyroid disorders.
- If you experience signs of associated vasculitis (inflammation of blood vessels) or tissue reactions (where the body's organs like the liver or kidneys become inflamed), such as liver problems (hepatitis), kidney issues, or very rarely seizures, stop taking LOPRICID immediately and permanently. These reactions can happen at any time during treatment.
- If you develop swollen lymph nodes and are diagnosed with angioimmunoblastic lymphadenopathy, this condition may improve after stopping LOPRICID.

Other medicines and **LOPRICID**

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 of the following:

- Medicines that can increase uric acid concentration, such as probenecid or aspirin or other salicylates used for pain and inflammation.
- Mercaptopurine, azathioprine, cyclophosphamide, doxorubicin, bleomycin and other anti-neoplastic medicines (used in the treatment of certain types of cancers).
- Some antibacterial medicines, such as ampicillin or amoxicillin (used to treat bacterial infections).

- Some anticoagulants, such as warfarin (used to prevent blood clotting).
- Some sulfonylurea antidiabetics, such as chlorpropamide (used in the management high blood sugar).
- Phenytoin (used in epilepsy or seizures).
- Theophylline (used in asthma or other respiratory disorders).
- Ciclosporin (used in organ transplants).
- Vidarabine (used in viral infections such as herpes simplex).
- Didanosine (used to treat HIV/AIDS).
- Diuretics, particularly thiazide diuretics (used to increase excretion of urine)
- Angiotensin-converting-enzyme (ACE) inhibitors (used in the treatment of high blood pressure)
- Aluminium hydroxide (used to treat gastric reflux)

Pregnancy, breastfeeding and fertility

You should not take LOPRICID if you are pregnant or breastfeeding your baby.

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.

Driving and using machines

LOPRICID can cause tiredness, light-headedness, dizziness and loss of coordination of voluntary muscle movements in some people. If this happens to you, avoid 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 LOPRICID 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 LOPRICID affects them.

LOPRICID 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 medicinal product.

3. How to take LOPRICID

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

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

Gout:

The usual dose is 50 mg twice daily and to increase this dose as required up to 200 mg to 400 mg daily in divided doses. If required, the scored tablet may be broken into two equal halves to obtain the required dose. Your doctor will decide on the correct dose, depending on your body's response.

LOPRICID should be taken after meals with water.

Hyperuricaemia associated with leukaemia:

The initial dose is 200 mg three times daily commencing, if possible, 2 or 3 days before radiotherapy. 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 LOPRICID.

If you have suffered from a liver or kidney disorder, your doctor will determine the suitable dose for you.

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

If you take more LOPRICID than you should

You may experience symptoms of nausea, vomiting, diarrhoea and dizziness. You should maintain an adequate level of hydration.

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

If you forget to take LOPRICID

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 LOPRICID at the next regularly scheduled time.

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

4. Possible side effects

LOPRICID can have side effects.

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

If any of the following happens, stop taking LOPRICID 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,
- blistering of the skin, mouth, eyes and genitals, as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

These are all very serious side effects. If you have them, you may have had a serious reaction to LOPRICID. 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 (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,
- paralysis (if you cannot move a specific part of your body, like your arms or legs),
- coma,
- 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.

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

Tell your doctor if you notice any of the following:

Frequent

- rash,
- increase in a thyroid hormone, which may suggest the thyroid is underactive (increased blood TSH).

Less frequent

- skin infections (furunculosis),
- cataract (clouding of the lens inside the eye),
- vision disturbances,
- vertigo (a spinning or whirling feeling),
- drowsiness, tiredness,
- nausea (feeling sick), vomiting (being sick), stomach pain, diarrhoea,
- taste disturbances,
- swelling and pain in the mouth,

- changes in your normal bowel habit,
- presence of fat in your stool,
- headache,
- temporary hair loss,
- discoloured hair,
- joint pain,
- sexual disorders including infertility and erection problems,
- fever,
- chills,
- swelling of the limbs,
- general feeling of weakness,
- high blood pressure,
- feeling abnormally sad (depression),
- high blood fat levels,
- involuntary muscle movements,
- inflamed blood vessels,
- low white blood cell count (leucopenia),
- high white blood cell count (leucocytosis),
- increased levels of a certain type of white blood cell, often linked to allergies (eosinophilia),
- a condition where red blood cells are breaking down too fast (haemolytic anaemia)
- very low white blood cell count (agranulocytosis)
- a condition when body does not make enough blood cells (aplastic anaemia)
- low platelet count (thrombocytopenia),
- swollen glands and immune system problems (angioimmunoblastic lymphadenopathy),
- changes in taste (dysgeusia),
- buildup of waste in the blood due to poor kidney function (uraemia or azotaemia),
- swelling of breast tissue in men (gynecomastia).

Frequency unknown

- inflammation around the brain (aseptic meningitis).

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 (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LOPRICID.

5. How to store LOPRICID

Store all medicines out of reach of children.

- Store at or below 25 °C
- Keep blisters in the outer carton until required for use.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label 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 LOPRICID contains

- LOPRICID 100

The active substance 100 mg allopurinol.

The other ingredients are anhydrous colloidal silica, crospovidone type B, isopropyl alcohol, lactose monohydrate, magnesium stearate, povidone PVP K30, pregelatinised starch, purified water.

- LOPRICID 300

The active substance 300 mg allopurinol.

The other ingredients are anhydrous colloidal silica, crospovidone type B, isopropyl alcohol, FD&C Yellow no.6-aluminum lake (LAKE PIGMENT HT), lactose monohydrate, magnesium stearate, povidone PVP K30, pregelatinised starch, purified water.

What LOPRICID looks like and contents of the pack

LOPRICID 100: White to off-white coloured, flat faced bevelled edged, round tablets, on one side debossed with "0" and "21" on either side of a scoreline and "100" on the other side.

LOPRICID 300: Peach coloured, flat faced bevelled edged, round tablets on one side
Debossed with "300" and "020" on either side of a scoreline and plain on the other side.

LOPRICID 100 and LOPRICID 300:

30 or 100 tablets in a blister pack comprises of forming rigid PVC film and plain Alu lidding foil. Blisters are packed in an outer carton with a printed leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

14 July 2026

Registration number

LOPRICID 100: 59/3.3/0761

LOPRICID 300: 59/3.3/0762

Access to the corresponding Professional Information

Website Address: www.trinitypharma.co.za