1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PURICOS-100 mg tablets

Allopurinol

Contains sugar: Lactose monohydrate 100 mg

PURICOS 300 mg tablets

Allopurinol

Contains sugar: Lactose monohydrate 180 mg

Read all of this leaflet carefully before you start taking PURICOS

- 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.
- PURICOS 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 PURICOS is and what it is used for
2. What you need to know before you take PURICOS
3. How to take PURICOS
4. Possible side effects
5. How to store PURICOS

6. Contents of the pack and other information

1. What PURICOS is and what it is used for

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

PURICOS is used to:

- prevent 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.
- prevent other conditions where there is a build-up of uric acid in the body. These include kidney stones and certain other types of kidney problem and when you are having treatment for cancer.

2. What you need to know before you take PURICOS

Do not take PURICOS:

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

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

Warnings and precautions

Take special care with PURICOS:

- PURICOS treatment should be stopped if any skin rash or allergic reaction occurs. Contact your doctor for advice if you develop a skin rash once starting treatment with PURICOS.
- 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.
- PURICOS should not be used to treat an acute attack of gout. PURICOS may cause an acute attack when starting treatment initially. Your doctor may prescribe additional medicines during the first month of PURICOS treatment.
- In children with Lesch-Nyhan syndrome. Increasing the daily fluid intake and taking urinary alkalinisers can reduce the side effects in these children.
- If you suffer from any urinary disorders. Consult your doctor for advice.

Other medicines and PURICOS

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

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

- Medicines that can increase uric acid concentration, such as aspirin or other salicylates used for pain and inflammation.
- Mercaptopurine, azathioprine and other anti-neoplastic medicines (used in the treatment of certain types of cancers).
- Some antibacterial medicines (used to treat bacterial infections).
- Some anticoagulants (used to prevent blood clotting).
- Some sulfonylurea antidiabetics (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).

PURICOS with food and drink

PURICOS should be taken after meals with water.

Pregnancy, breastfeeding and fertility

You should not take PURICOS 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 healthcare provider for advice before taking this medicine.

Driving and using machines

PURICOS can cause vision tiredness, light-headedness and dizziness 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 PURICOS 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 PURICOS affects them (see section 4).

PURICOS contains lactose monohydrate

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

3. How to take PURICOS

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

Always use PURICOS exactly as your doctor has told you.

You should 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. 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 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 PURICOS.

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

If you take more PURICOS than you should

In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take PURICOS

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 PURICOS at the next regularly scheduled time.

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

4. Possible side effects

PURICOS can have side effects.

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

If any of the following happens, stop taking PURICOS 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 PURICOS. 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,
- paralysis (if you cannot move a specific part of your body, like your arms or legs),
- coma,
- fainting,
- 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 side effects:

- Rash.

Less frequent side effects:

- 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,
- muscle 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).

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 "**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 PURICOS.

5. How to store PURICOS

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep container tightly closed.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What PURICOS contains

PURICOS-100: The active substance is 100 mg of allopurinol.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, pregelatinised starch, polysorbate, purified talc, sodium starch glycollate.

PURICOS 300: The active substance is 300 mg of allopurinol.

The other ingredients are croscarmellose sodium, lactose monohydrate, maize starch, povidone.

What PURICOS looks like and contents of the pack

PURICOS-100: A white, round, shallow, biconvex tablet, bisected on one side, with a diameter ranging between 9,0 mm to 10,0 mm.

PURICOS 300: PURICOS 300: A white, round, shallow, biconvex tablet, bisected on one side, with a diameter ranging between 10,6 mm to 11,7 mm.

PURICOS-100: 100 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. One or more blister strips are packed into an outer cardboard carton together with a leaflet.

PURICOS-100: 500 tablets are packed in a white polypropylene container and sealed with a white low density polyethylene cap with a tamper evident seal, together with a white foam insert or rayon, together with a leaflet.

PURICOS-100: 30 tablets are packed in a metallised polyester patient ready lay flat pack and sealed with a clear low density polyethylene zip. The lay flat is overwrapped with a clear polyethylene bag.

PURICOS 300: 30 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. One or more blister strips are packed into an outer cardboard carton together with a leaflet.

PURICOS 300: 250 tablets are packed in a white polypropylene container and sealed with a white low density polyethylene cap with a tamper evident seal, together with a white foam insert or rayon, together with a leaflet.

PURICOS 300: 28 or 30 tablets are packed in a metallised polyester patient ready lay flat pack and sealed with a clear low density polyethylene zip.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912

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PURICOS-100: K/3.3/305

PURICOS 300: L/3.3/257

Access to the corresponding Professional Information

12 August 2020

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