

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

ALLOPURINOL 100 KIARA Tablets

ALLOPURINOL 300 KIARA Tablets

Active ingredient: Allopurinol

Contains Sugar (Lactose)

Please read this leaflet carefully before you start taking ALLOPURINOL KIARA tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ALLOPURINOL KIARA 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 KIARA is and what it is used for
2. What you need to know before you take ALLOPURINOL KIARA
3. How to take ALLOPURINOL KIARA
4. Possible side effects
5. How to store ALLOPURINOL KIARA
6. Contents of the pack and other information

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

There are two strengths available: ALLOPURINOL 100 KIARA, which contains 100 mg of allopurinol (the active ingredient) and ALLOPURINOL 300 KIARA, which contains 300 mg of allopurinol.

ALLOPURINOL KIARA is used in the treatment of gout (inflammation in tissue and joints due to a deposition of urate crystals in these areas).

Each ALLOPURINOL 100 KIARA tablet contains sugar (lactose 85 mg).

Each ALLOPURINOL 300 KIARA tablet contains sugar (lactose 65 mg).

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

Do not take ALLOPURINOL KIARA:

- If you are hypersensitive (allergic) to allopurinol or any of the ingredients.
- If you suffer from severe hepatic (liver) or renal (kidney) dysfunction.
- ALLOPURINOL KIARA should not be given to children or mothers who are breast feeding their babies. However, if children and breast feeding woman have been diagnosed with cancer and the doctor has prescribed this medication, it should be used as directed.
- Do not start taking ALLUPURINOL KIARA during an acute attack of gout or within 4 weeks of the attack.

Warnings and precautions

Take special care with ALLOPURINOL KIARA:

- If you have a tumour. Your doctor will perform certain tests to ensure that your uric acid levels are normal before starting you on immune suppressant medication (methotrexate).
- If you suffer from kidney dysfunction. Allopurinol may be effective longer than usual since the excretion is affected. The dosing frequency may have to be decreased. Your doctor also needs to be informed if you are undergoing renal dialysis.
- If you have any liver dysfunction.

Other medicines with ALLOPURINOL KIARA

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

- Mercaptopurine (agent used in the treatment of cancer) and azathioprine (immunosuppressant medication used after organ transplants).
- Probenecid (gout treatment) and large doses of salicylate (aspirin).
- Chlorpropamide (used in the treatment of high blood sugar).
- Blood thinning tablets e.g. warfarin.
- Diazoxide and mecamlamine (both used in the treatment of high blood pressure) or pyrazinamide (tuberculosis agent).
- Alkalinisation of the urine (bicarbonate salts) and urine acidifiers (vitamin C).
- Asthmatic treatment for example: theophylline, aminophylline or oxtriphylline (the effect of these agents will be extended, and dosage adjustments may be required).

The use of iron supplements with ALLOPURINOL KIARA is not recommended in patients with a blood disease called haemochromatosis.

The use of allopurinol **before starting treatment** with bleomycin, doxorubicin, procarbazine (cancer treatment), can reduce the complications associated with these cancer medications.

However, the use of allopurinol **together with** cyclophosphamide and other anti-cancer agents can lead to bone-marrow suppression.

ALLOPURINOL KIARA with food and drink:

Avoid large amounts of alcohol since it may increase your uric acid concentrations and reduce the effectiveness of these tablets.

Pregnancy and Breastfeeding:

ALLOPURINOL KIARA should not be used if you are pregnant. If you are breast-feeding your baby, the use of these tablets is not advised, except if you have cancer and the doctor has prescribed this medication to you.

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

ALLOPURINOL KIARA contains sugar (Lactose)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using ALLOPURINOL KIARA.

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

3. How to take ALLOPURINOL KIARA

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

Always take ALLOPURINOL KIARA exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

Initial treatment should be 50 mg (half a ALLOPURINOL 100 KIARA) twice daily after meals followed by a dosage increase up to 200 to 400 mg daily in divided doses or as a single dose. The usual dose is 300 mg/day. Up to 600 mg daily may be required in severe gout. The maximum recommended dose is 800 mg daily. This dosage should not be exceeded. Fluid intake should be more than 2 litres daily.

Children under 15 years:

Commence treatment with 8 mg/kg body mass daily. The dose may be increased to 20 mg/kg body mass daily (maximum 400 mg daily).

These tablets are rarely used by children, except if they were diagnosed with cancer, especially leukaemia and certain enzyme disorders e.g. Lesch-Nyhan syndrome. The dose should be adjusted according to the uric acid blood levels as determined by the doctor.

It is recommended that allopurinol be taken after meals for better tolerance.

If you are suffering from kidney or liver dysfunctions, your dosage will be adjusted by your doctor according to your requirements.

If you have the impression that the effect of ALLOPURINOL KIARA is too strong or too weak, talk to your doctor or pharmacist.

If you take more ALLOPURINOL KIARA than you should

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

The most likely reaction would be gastrointestinal intolerance. Adequate intake of fluids will facilitate the excretion of allopurinol and its metabolites. Dialysis may be resorted to if considered necessary.

If you forget to take ALLOPURINOL KIARA

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

4. Possible side effects

ALLOPURINOL KIARA can have side effects. Not all side effects reported for ALLOPURINOL KIARA 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 health care professional for advice.

After starting ALLOPURINOL KIARA treatment for gout, the most commonly encountered adverse event is a temporary increase in the frequency of attacks. The frequency will decrease after continuous treatment.

If any of the following happen, stop taking ALLOPURINOL KIARA and tell your doctor immediately.

- Skin hives, rash or itching (frequently encountered).
- Fever with or without chills, sores, ulcers, sore throat, muscle aches and pains, unusual bruising or bleeding (rarely encountered).
- Unusual tiredness and/or weakness (rarely encountered).

- Yellow eyes or skin (rarely encountered).
- Loosening of fingernails (rarely encountered).
- Nausea and vomiting (rarely encountered).
- Blood in the urine and painful urination (rarely encountered).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to allopurinol. You may need urgent medical attention or hospitalization.

Inform your doctor if any of the following side effects become bothersome.

- Diarrhoea, drowsiness, headache, indigestion and unusual hair loss.

All of these side effects have occurred less frequently.

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 ALLOPURINOL KIARA.

5. How to store ALLOPURINOL KIARA

- Keep well closed in a dark, dry place at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the blisters and containers. Decomposed products may be toxic.
- 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 ALLOPURINOL KIARA contains

- The active substance is allopurinol.

The other inactive ingredients: lactose, maize starch, povidone and magnesium stearate.

What ALLOPURINOL KIARA looks like and contents of the pack

ALLOPURINOL 100 KIARA: White, round, flat, bevel-edged tablet, scored on the one side.

ALLOPURINOL 300 KIARA: White, round, biconvex tablet, scored on the one side.

ALLOPURINOL 100 KIARA: Blister packs, securitainers or amber glass bottles of 30 or 500 tablets.

ALLOPURINOL 300 KIARA: Blister packs, securitainers or amber glass bottles of 28,30, 250 or 300 tablets.

Holder of Certificate of Registration

Kiara Health (Pty) Ltd
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South Africa

This leaflet was last revised in

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Registration Numbers

ALLOPURINOL 100 KIARA: P/3.3/180

ALLOPURINOL 300 KIARA: P/3.3/181

Additional countries registration details:

<i>Country</i>	<i>Product name</i>	<i>Scheduling status (or Category of distribution)</i>	<i>Registration number</i>
Botswana	ALLOPURINOL KIARA 100	S2	B9308750
	ALLOPURINOL KIARA 300	S2	B9308755
Mauritius	ALLOPURINOL KIARA 300		R2510/02/14
Namibia	ALLOPURINOL KIARA 100	NS2	90/3.3/001444
	ALLOPURINOL KIARA 300	NS2	90/3.3/001445

ATC code: M04AA01 – Preparations inhibiting uric acid production

Name and address of manufacturer:

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