

Allopurinol Sandoz®

allopurinol tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Allopurinol Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ALLOPURINOL SANDOZ IS USED FOR

This medicine is used to treat or prevent medical problems that may occur if too much uric acid is present in the body.

These include gout, gouty arthritis, certain kidney problems or enzyme disorders where the body produces too much uric acid.

It contains the active ingredient allopurinol.

Allopurinol belongs to a group of medicines called xanthine oxidase inhibitors.

It works by reducing the production of uric acid in the body, therefore

helping to prevent the formation of deposits of uric acid crystals.

Deposits of uric acid crystals in the body can cause a variety of medical problems.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE ALLOPURINOL SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- allopurinol, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- hay fever
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.
- muscle pain or tenderness or joint pain

If you think you are having an allergic reaction, do not take any more of the medicine and contact

your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Do not take this medicine if you or a member of your immediate family has haemochromatosis, a condition where there is too much iron in the body, and you are also taking iron salts at the same time.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease
- liver disease
- heart disease or high blood pressure
- conditions where the levels of uric acid are abnormally high
- cancers or tumours
- thyroid problems
- diabetes
- epilepsy
- haemochromatosis, a condition where there is too much iron in the body
- any other medical conditions.

Tell your doctor if you are currently having an acute attack of gout.

Treatment with allopurinol should not be started until the attack has stopped, otherwise more attacks may occur.

(However, if an attack of gout occurs when a person is already taking allopurinol, it can be continued).

Tell your doctor if you are taking medicines to treat cancer.

Your doctor may need to do regular blood tests if you are being treated with cyclophosphamide, doxorubicin, bleomycin, procarbazine or alkyl halogenides.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Allopurinol passes into breast milk and may affect your baby. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Allopurinol Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Allopurinol Sandoz may interfere with each other. These include:

- some medicines used to treat high blood pressure or heart problems
- medicines used for cancer (e.g. cyclophosphamide, doxorubicin)
- didanosine, used to treat HIV infection
- adenine arabinoside, a medicine used to treat viral infections
- azathioprine, mercaptopurine and cyclosporin, medicines used to suppress the immune system
- chlorpropamide, a medicine used to treat diabetes
- aspirin (a drug which is used to treat headache, pain, inflammation, clotting or high

temperatures) and other salicylates

- other medicines used to treat gout or hyperuricaemia (high levels of uric acid in the blood), such as probenecid
- ampicillin or amoxycillin, antibiotic medicines used to treat bacterial infections
- warfarin and other coumarin type anticoagulant medicines used to prevent blood clots
- thiazide diuretics (a certain type of water tablet)
- phenytoin, a medicine used to treat epilepsy
- theophylline, a medicine used to treat asthma.
- medicines containing aluminium hydroxide, used to treat heartburn, upset stomach or indigestion.

These medicines may be affected by Allopurinol Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Other medicines not listed above may also interact with allopurinol.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE ALLOPURINOL SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Allopurinol Sandoz may not work as well and your problem may not improve.

The recommended daily doses are:

Adults:

100mg to 600mg daily.

If the dose is more than 300mg each day, it is recommended that half the dose is taken in the morning and half is taken at night (divided doses).

The dose may be as much as 900mg a day to treat very high levels of uric acid.

Children under 15 years:

100mg to 400mg daily in divided doses.

Elderly patients:

Elderly patients usually receive the lowest dose possible to control uric acid production.

How to take it

Swallow the tablets whole with a full glass of water.

When to take Allopurinol Sandoz

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take your medicine during or immediately after a meal.

If you take it on an empty stomach, it may increase the possibility of feeling sick or causing a stomach upset.

How long to take Allopurinol Sandoz

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Allopurinol Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- diarrhoea
- dizziness.

WHILE YOU ARE TAKING ALLOPURINOL SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Allopurinol Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you develop a skin rash or any other allergic reaction, stop taking Allopurinol Sandoz and seek medical attention immediately.

Tell your doctor if you have an acute attack of gout while you are taking allopurinol.

Your doctor may prescribe a medicine to relieve the acute attack. You can continue taking allopurinol.

Drink plenty of water (at least 8-10 glasses of fluid per day) while you are taking Allopurinol Sandoz.

This will assist in reducing the uric acid levels in your body and prevent kidney stones from forming.

If you are going to have surgery, tell your surgeon or anaesthetist that you are taking this medicine.

If you are about to have any blood tests, tell your doctor you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Allopurinol Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without

checking with your doctor, unless a skin rash or allergic reaction occurs.

If you stop taking it suddenly, your condition may worsen. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not take this medicine to treat an acute attack of gout.

Things to be careful of

Be careful driving or operating machinery until you know how Allopurinol Sandoz affects you.

This medicine may cause drowsiness, dizziness and lack of co-ordination in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness, dizziness and blurred vision may be worse.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Allopurinol Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The most common side effect is skin rash. Stop treatment with Allopurinol Sandoz immediately and contact your doctor if a rash does occur.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea (feeling sick) or vomiting or diarrhoea
- dizziness, drowsiness or unsteadiness when walking
- headache
- taste changes
- sleeplessness
- hair loss or change in hair colour

Tell your doctor as soon as possible if you notice any of the following:

- changes in vision
- tingling or numbness of the hands or feet
- a change in the amount of urine passed, going to the toilet more often or burning feeling when passing urine
- blood in your urine
- yellow of the skin and eyes (jaundice)
- generally feeling of being unwell or depressed
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily
- swelling of the hands, ankles or legs
- angina or palpitations.

If any of the following happen, tell your doctor immediately:

- skin rash, itching or hives on the skin
- sudden or severe itching
- swelling of the face, lips, tongue or other parts of the body which may cause difficulty in breathing
- asthma, wheezing, shortness of breath, or trouble breathing
- pain or tightness in the chest,
- fainting, seizures or fits.

The above are very serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare, although skin rash and itching are more common side effects.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

AFTER TAKING ALLOPURINOL SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Allopurinol Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Allopurinol Sandoz comes in two types of tablets:

Allopurinol Sandoz 100mg - white, round tablets with a score notch on one side.

Available in bottles of 200 tablets.

Allopurinol Sandoz 300mg - white, oblong tablets, scored on both sides.

Available in bottles of 60 tablets.

Ingredients

Active ingredients:

- Allopurinol Sandoz 100mg - 100mg allopurinol.
- Allopurinol Sandoz 300mg - 300mg allopurinol.

Inactive ingredients:

- powdered cellulose
- povidone
- macrogol 4000
- crospovidone
- purified talc
- magnesium stearate
- microcrystalline cellulose.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

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