


<p>Package leaflet: Information for the user</p> <p>Allopurinol 100 mg Tablets</p> <p>Read all of this leaflet carefully before you start using this medicine because it contains important information for you.</p> <ul style="list-style-type: none">• Keep this leaflet. You may need to read it again.• If you have any further questions, ask your doctor or pharmacist.• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.• If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.	<p>Other medicines and Allopurinol</p> <p>Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, including herbal medicines. This is because allopurinol can affect the way some medicines work.</p>
<p>What is in this leaflet</p> <ol style="list-style-type: none">1. What Allopurinol is and what it is used for2. What you need to know before you take Allopurinol3. How to take Allopurinol4. Possible side effects5. How to store Allopurinol6. Contents of the pack and other information <p>1. What Allopurinol is and what it is used for</p> <ul style="list-style-type: none">• Allopurinol belongs to a group of medicines called enzyme inhibitors, which act to control the speed at which special chemical changes occur in the body.• Allopurinol is used for the long term, preventative treatment of gout and may be used in other conditions associated with an excess of uric acid in the body, including kidney stones and other types of kidney disease.	<p>It is especially important to tell your doctor if you are taking any of the medicines listed below. Your doctor may need to reduce the dose of your medicine and/or monitor you more carefully because of the increased risk of side effects when Allopurinol Tablets is taken at the same time as:</p> <ul style="list-style-type: none">• other medication to treat gout e.g. probenecid• large doses of aspirin-type drugs (salicylates)• medicines for high blood pressure or heart disease such as diuretics ("water tablets") e.g. furosemide, or ACE inhibitors e.g. fosinopril, captopril• any medicines used to thin your blood (anticoagulants) e.g. warfarin• 6-mercaptopurine (used to treat blood cancer)• ciclosporin or azathioprine (used to suppress the immune system)• didanosine (used to treat HIV infections)• chlorpropamide (used to treat diabetes)• vidarabine (adenine arabinoside), used in the treatment of herpes• phenytoin (used to treat epilepsy)• theophylline (used for respiratory problems)• the antibiotics amoxicillin or ampicillin• cyclophosphamide, doxorubicin, bleomycin, procarbazine, mechlorethamine or any other anti-cancer medication.
<p>2. What you need to know before you take Allopurinol</p> <p>Do not take Allopurinol if you:</p> <ul style="list-style-type: none">• are allergic to Allopurinol or any of the other ingredients of this medicine (listed in section 6)• are currently having an attack of gout or have just had an attack of gout.	<p>The co-administration of 6-mercaptopurine or azathioprine with allopurinol should be avoided. When 6-mercaptopurine or azathioprine is given concurrently with this medicine, the dose of 6-mercaptopurine or azathioprine should be reduced because their activity will be prolonged. This could increase the risk of serious blood disorders. In this case, your doctor will closely monitor your blood count during treatment.</p>
<p>Warnings and precautions</p> <p>Talk to your doctor or pharmacist before taking your medicine if you:</p> <ul style="list-style-type: none">• are of Han Chinese, African or Indian origin.• 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. They will also monitor you more closely.• have heart problems or high blood pressure and you take diuretics and/or a medicine called ACE-inhibitors.• are currently having an attack of gout or have just had an attack of gout.• have thyroid problems.	<p>Seek medical advice immediately if you notice that you have any unexplained bruising, bleeding, fever or sore throat.</p> <p>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.</p>
<p>Take special care with Allopurinol:</p> <p>Talk to your doctor before taking Allopurinol if you:</p> <ul style="list-style-type: none">• are suffering from, or have previously suffered from any form of liver or kidney disease. Your doctor may give you a lower dose or ask you to take it less often than each day. They will also monitor you closely• have heart problems or have high blood pressure• are pregnant or trying to become pregnant.	<p>With administration of allopurinol 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.</p>
<p>If you develop a rash or these skin symptoms, stop taking Allopurinol, seek urgent advice from a doctor and tell him that you are taking this medicine:</p> <ul style="list-style-type: none">• Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Allopurinol, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.• Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).• These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.• The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.• If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Allopurinol, you must not be re-started on Allopurinol at any time.	<p>Pregnancy and breast-feeding</p> <p>If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.</p> <p>Allopurinol is excreted in the human breast milk. Allopurinol during breastfeeding is not recommended.</p> <p>Driving and using machines</p> <p>Allopurinol can cause dizziness, drowsiness and can affect your coordination. If you are affected DO NOT drive, operate machinery or participate in dangerous activities.</p> <p>Important information about some of the ingredients of Allopurinol</p> <p><i>Lactose</i></p> <p>If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.</p> <p><i>Sodium</i></p> <p>This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.</p> <p>3. How to take Allopurinol</p> <p>Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.</p>
<p>Serious skin rashes have been reported with the use of allopurinol that can be more common in patients with chronic renal impairment and in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients additionally. These serious skin rashes can include hypersensitivity syndrome, Stevens- Johnson syndrome and toxic epidermal necrolysis. All have been reported with the use of allopurinol. Frequently, the rash can involve 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.</p> <p>If you develop a rash or these skin symptoms, stop taking allopurinol 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.</p> <p>In case you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.</p>	<p>The tablets should preferably be taken with a drink of water. You should take your tablets after a meal. You should drink plenty of fluids (2-3 litres a day) while you are taking this medicine.</p> <p>The score line is only there to help you break the tablet if you have difficulty swallowing it whole.</p> <p>The recommended dose is:</p> <ul style="list-style-type: none">• Adults (including the elderly) <p>Your doctor will usually start with a low dose of allopurinol (e.g. 100 mg/day), to reduce the risk of possible side effects. Your dose will be increased if necessary. When you start your treatment, your doctor may also prescribe an anti-inflammatory medicine or colchicine for a month or more, to prevent attacks of gouty arthritis.</p> <p>Your dose of allopurinol may be adjusted depending on the severity of the condition. The maintenance dose is:</p> <ul style="list-style-type: none">• mild conditions, 100-200 mg/day• moderately severe conditions, 300-600 mg/day• severe conditions, 700-900 mg/day.

<p>Your dose may also be altered by your doctor if you have reduced kidney and liver function, particularly if you are elderly.</p> <p>If the daily dose exceeds 300 mg/day and you are suffering from gastro-intestinal side effects such as nausea or vomiting (see section 4), your doctor may prescribe allopurinol in divided doses to reduce these effects.</p> <ul style="list-style-type: none"> Children (under 15 years) 100 - 400 mg/day. Treatment may be started together with an anti-inflammatory medicine or colchicine, and the dose adjusted if you have reduced kidney and liver function, or divided to reduce gastro-intestinal side effects, as for Adults above. <p>If you take more Allopurinol than you should If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause effects including nausea, vomiting, diarrhoea, or dizziness. Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.</p> <p>If you forget to take Allopurinol If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.</p> <p>If you stop taking Allopurinol You should continue to take these tablets for as long as your doctor tells you to. DO NOT stop taking your medicine without talking to your doctor first.</p> <p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p> <p>4. Possible side effects Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> <p>Stop taking Allopurinol and contact your doctor immediately or go to your nearest hospital casualty department if you experience: The following common side effects (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none"> skin rashes (see section 2). <p>The following rare side effects (may affect up to 1 in 1,000 people):</p> <ul style="list-style-type: none"> fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell bleeding in the lips, eyes, mouth, nose or genitals. any changes to your skin, for example ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes), widespread blisters or peeling serious hypersensitivity reactions involving fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder). <p>The following very rare side effects (may affect up to 1 in 10,000 people):</p> <ul style="list-style-type: none"> potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) (see section 2) serious allergic reaction which causes swelling of the face or throat serious potentially life-threatening allergic reaction. <p>The signs of a serious allergic reaction can also include:</p> <ul style="list-style-type: none"> an unexpected skin reaction (possibly in association with fever, swollen glands, joint pain, unusual blistering or bleeding, kidney problems (blood in the urine) or a sudden onset of fits) swelling of the hands, lips, tongue difficulty swallowing or breathing sudden wheeziness. <p>The following not known side effects (cannot be estimated from available data):</p> <ul style="list-style-type: none"> Aseptic meningitis (inflammation of the membranes that surround the brain and spinal cord): symptoms include neck stiffness, headache, nausea, fever or consciousness clouding. Seek medical attention immediately if these occur. Lichenoid skin rash (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes) <p>If you experience any of the following while you are taking Allopurinol, stop taking your tablets and tell your doctor as soon as possible: The following common side effects have been reported (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none"> increased level of thyroid stimulating hormone in the blood. <p>The following uncommon side effects have been reported (may affect up to 1 in 100 people):</p> <ul style="list-style-type: none"> nausea, vomiting (very rarely, blood may be present) and diarrhoea. <p>The following rare side effects have been reported (may affect up to 1 in 1,000 people):</p> <ul style="list-style-type: none"> jaundice (yellowing of the skin and whites of the eyes) may affect your liver or kidney function (diagnosed by blood and/or urine tests) formation of stones in the urinary tract, symptoms may include blood in the urine and pain in the abdomen, flank, or groin. 	<p>The following very rare side effects have been reported (may affect up to 1 in 10,000 people):</p> <ul style="list-style-type: none"> reduction in the number of white blood cells, which makes infections more likely reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia) high temperature lethargy blood in the urine (haematuria) a change in your normal bowel habit, or unusual foul-smelling bowel movements high fat levels in the blood (diagnosed by blood tests) a general feeling of being unwell weakness, numbness, unsteadiness on feet, inability to move muscles (paralysis) or loss of consciousness, pins and needles sleepiness difficulty in controlling movements (ataxia) convulsions, fits or depression coma headache, feeling of dizziness or spinning, drowsiness or disturbance of vision chest pain, high blood pressure or a slow pulse vomit blood (haematemesis) retention of fluid leading to swelling (oedema) particularly of the ankles male infertility (inability to achieve a pregnancy after one year of regular contraceptive-free intercourse) inability to get or maintain an erection, or ejaculation during sleep ("wet dreams") enlargement of the breasts, in men as well as women a change in taste perception, inflammation in the mouth cataracts (clouding of the lens of the eye) boils (small tender red lumps on the skin) hair loss or discolouration feeling thirsty, tired and losing weight (these may be symptoms of diabetes), your doctor may wish to measure the level of sugar in your blood to decide if this is happening muscle pain occasionally Allopurinol 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. Tell your doctor as soon as possible. <p>You may occasionally feel sick, but this can usually be avoided by taking allopurinol after meals. Tell your doctor if this problem persists.</p> <p>Occasionally, allopurinol may affect your blood or lymphatic system. These effects have usually occurred in people with liver or kidney problems. Tell your doctor as soon as you can if you notice that you are bruising more easily than usual, or if you develop a sore throat or other signs of an infection.</p> <p>If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.</p> <p>Reporting of side effects If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.</p> <p>5. How to store Allopurinol Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original package. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.</p> <p>6. Contents of the pack and other information What Allopurinol contains:</p> <ul style="list-style-type: none"> Each 100 mg tablet contains 100 mg of Allopurinol The other ingredients are lactose monohydrate, colloidal anhydrous silica, maize starch, powdered cellulose, sodium starch glycolate, sodium laurilsulfate, povidone and magnesium stearate. <p>What Allopurinol looks like and contents of the pack:</p> <ul style="list-style-type: none"> Allopurinol 100 mg Tablets are white, round, biconvex tablets, debossed "4K1 4K1" on one side and with a breakline on both sides. The 100 mg tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 250 and 500 tablets. Not all pack sizes may be marketed. <p>Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom</p> <p>Manufacturer: Teva Pharmaceutical Works Private Limited Company, 13 Pallagi H- 4042, Debrecen, Hungary.</p> <p>This leaflet was last revised: December 2024</p> <p>PL 00289/0951  222226_s1</p>
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