

Package leaflet: Information for the user

Allopurinol Teva 100 mg and 300 mg Tablets Allopurinol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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.

What is in this leaflet

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

1. What Allopurinol Teva is and what it is used for

- Allopurinol Teva 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 Teva tablets are used for the long term, preventive 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.

2. What you need to know before you take Allopurinol Teva

Do not take Allopurinol Teva:

- if you are allergic to allopurinol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Allopurinol Teva if:

- you have problems with your liver and 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.
- you have heart problems or high blood pressure and if you are taking diuretics and/or a medicine called ACE inhibitor.
- you are currently having an attack of gout.
- you are of Han Chinese, Thai or Korean origin.
- you have thyroid problems.

Serious skin rashes have been reported with the use of allopurinol that can be more common in patients with chronic renal impairment. 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. These serious skin reactions can be more common in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients additionally.

If you develop a rash or these skin symptoms, **stop taking allopurinol and contact your doctor immediately.**

If you have kidney stones, they will become smaller and may have a small chance of entering and blocking your urinary tract.

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.

Other medicines and Allopurinol Teva

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

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

- 6-mercaptopurine (used to treat blood cancer)
- azathioprine, ciclosporin (used to suppress the immune system)
Please note, ciclosporin side effects may occur more frequently.
- vidarabine (used in the treatment of herpes)
Please note, vidarabine side effects can occur more frequently. Take special care if these occur.
- salicylates (used to reduce pain, fever or inflammation e.g. acetylsalicylic acid)
- probenecid (used to treat gout)
- chlorpropamide (used to treat diabetes)
Chlorpropamide dose reduction may be necessary, particularly in patients with reduced kidney function.
- warfarin, phenprocoumon, acenocoumarol (used to thin the blood)
Your doctor will monitor your blood clotting values more frequently and if necessary, reduce the dose of these medicines.
- phenytoin (used to treat epilepsy)
- theophylline (used to treat asthma and other breathing diseases)
Your doctor will measure theophylline blood levels, particularly when treatment with allopurinol begins, or following any dosage changes.
- ampicillin or amoxicillin (used to treat bacterial infections)
Patients should receive other antibiotics where possible, as allergic reactions are more likely to occur.
- cytostatics (used to treat aggressive tumours)
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..
- didanosine (used to treat HIV infection)
- ACE inhibitors or diuretics (water tablets) (used to treat heart problems or high blood pressure)
The risk of skin reactions can be raised, especially if your kidney function is chronically reduced.
- aluminium hydroxid (used to neutralise the acid in the stomach)
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.

Pregnancy and breast-feeding

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.

You should not take this medicine if you are pregnant unless advised by your doctor.

Allopurinol is excreted in the human breast milk. Allopurinol during breast-feeding is not recommended.

Driving and using machines

Allopurinol Teva tablets can cause dizziness, drowsiness, and can affect your coordination. If you are affected, DO NOT drive, operate machinery or participate in dangerous activities.

Allopurinol Teva contains lactose

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

Allopurinol Teva contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Allopurinol Teva

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

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.

The recommended dose is:

Adults (including the elderly)

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.

Your dose of allopurinol may be adjusted depending on the severity of the condition. The maintenance dose is:

- mild conditions, 100-200 mg/day
- moderately severe conditions, 300-600 mg/day
- severe conditions, 700-900 mg/day.

Your dose may also be altered by your doctor if you have reduced kidney and liver function, particularly if you are elderly.

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.

If you have a serious kidney problem

- you may be asked to take less than 100 mg each day
- or you may be asked to take 100 mg at longer intervals than one day

If you have dialysis two or three times a week, your doctor may prescribe a dose of 300 or 400 mg which is to be taken straight after your dialysis.

Use in children (under 15 years)

100 - 400 mg/day given as 3 divided doses.

Use in children is rarely indicated except in some types of cancer, especially in leukaemia and certain enzyme disorders, for example Lesch-Nyhan syndrome.

Allopurinol Teva 100 mg tablets and Allopurinol Teva 300 mg tablets:

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Allopurinol Teva 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.

If you forget to take Allopurinol Teva

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.

If you stop taking Allopurinol Teva

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following, stop taking the medicine and/or tell your doctor immediately:

- an unexpected skin reaction (possibly in association with fever, swollen glands, joint pain, unusual blistering or bleeding, kidney problems or a sudden onset of fits).
- skin rashes are the most common side effect with allopurinol (may affect up to 1 in 10 people).

Rare (may affect up to 1 in 1,000 people)

- fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell
- any changes to your skin, for example ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes), widespread blisters or peeling
- bleeding in the lips, eyes, mouth, nose or genitals
- 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).

Very rare (may affect up to 1 in 10,000 people)

- serious allergic reaction which causes swelling of the face or throat
- serious potentially life-threatening allergic reaction

If you have an allergic reaction, stop taking allopurinol and see a doctor straight away. The signs may include:

- skin rash, flaking skin, boils or sore lips and mouth.
- swelling of the face, hands, lips, tongue or throat.
- difficulty swallowing or breathing.
- very rarely signs may include sudden wheeziness, fluttering or tightness of the chest and collapse.

Do not take any more tablets unless your doctor tells you to do so.

Not known (frequency cannot be estimated from available data)

- 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.

If you experience any of the following while you are taking Allopurinol Teva, tell your doctor as soon as possible:

The following **common** side effects have been reported (may affect up to 1 in 10 people):

- increased level of thyroid stimulating hormone in the blood

The following **uncommon** side effects have been reported (may affect up to 1 in 100 people):

- stomach pain, nausea, vomiting (very rarely, blood may be present) and diarrhoea
- symptoms of allergic reactions including itchy rash
- increase in results of liver function tests

The following **rare** side effects have been reported (may affect up to 1 in 1,000 people):

- joint pain or painful swelling in the groin, armpits or neck
- inflammation of the liver (hepatitis), jaundice (yellowing of the skin and whites of the eyes)
- your liver or kidney function may be affected

- formation of stones in the urinary tract, symptoms may include blood in the urine and pain in the abdomen, flank, or groin

The following **very rare** side effects have been reported (may affect up to 1 in 10,000 people):

- high temperature
- blood in the urine
- a change in your normal bowel habit, or unusual foul-smelling bowel movements
- high fat levels in the blood
- a general feeling of being unwell
- weakness, numbness, unsteadiness on feet, inability to move muscles (paralysis) or loss of consciousness
- lack of voluntary coordination of muscle movements (ataxia)
- pins and needles (paraesthesia)
- convulsions, fits or depression
- headache, dizziness, drowsiness or disturbance of vision
- chest pain, high blood pressure or a slow pulse
- retention of fluid leading to swelling (oedema) particularly of the ankles
- male infertility or 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) and other problems with sight
- 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
- swollen glands, usually goes away once treatment with allopurinol ends
- 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.

You may occasionally feel sick, but this can usually be avoided by taking allopurinol after meals. Tell your doctor if this problem persists.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allopurinol Teva

Transparent aluminium blisters

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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.

HDPE Bottles

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Store in the original packaging.

Keep the bottle tightly closed in order to protect from light.

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.

6. Content of the pack and other information

What Allopurinol Teva contains

- The active substance is allopurinol.
Each 100 mg tablet contains 100 mg allopurinol.
Each 300 mg tablet contains 300 mg allopurinol.
- The other ingredients are lactose monohydrate, silica colloidal anhydrous, maize starch, powdered cellulose, sodium starch glycolate (Type A), sodium laurilsulfate, povidone K30 and magnesium stearate (E470b).

What Allopurinol Teva looks like and contents of the pack

- Allopurinol Teva 100 mg tablets are white, round, biconvex tablets, debossed “4K1 4K1” on one side and break line on both sides.
- Allopurinol Teva 300 mg tablets are white, round, biconvex tablets, debossed “2K1 2K1” on one side and break line on the other side.

The product is available in transparent aluminium blisters in the following pack sizes :

Allopurinol Teva 100 mg tablets: 20, 25, 28, 30, 50, 60, 90, 98, 100, 105 and 500 tablets and Hospital Pack of 50

Allopurinol Teva 300 mg tablets: 20, 28, 30, 50, 60, 90, 98, 100, 105 and 500 tablets and Hospital Pack of 50

The product is also available in HDPE Bottles in the following pack sizes:

Allopurinol Teva 100 mg tablets: 30 Tablets in 35 ml Bottle or 100 Tablets in 35 ml Bottle

Allopurinol Teva 300 mg tablets: 30 Tablets in 35 ml Bottle or 100 Tablets in 100 ml Bottle

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturers

TEVA Pharmaceutical Works Private Limited Company
Pallagi út 13,
4042 Debrecen
Hungary

Pharmachemie B.V.
Swensweg 5,
2031 GA Haarlem
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Allopurinol TEVA 100 and 300 mg tabletten

Bulgaria: ALODAGRA 100 mg tablets

Denmark: Allopurinol “Teva”

France: Allopurinol Teva 100, 200 and 300 mg, comprimé

Ireland: Allopurinol Teva 100 and 300 mg tablets

Italy: Allopurinolo Teva Italia 100 and 300 mg compresse

The Netherlands: Allopurinol 100, 200 and 300 mg PCH, tabletten

Sweden: Allopurinol Teva 100 and 300 mg tabletter

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