

**PACKAGE LEAFLET:
INFORMATION FOR THE USER
Allopurinol Tablets BP
100mg and 300mg
[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 Tablets are and what they are used for
2. What you need to know before you take Allopurinol Tablets
3. How to take Allopurinol Tablets
4. Possible side effects
5. How to store Allopurinol Tablets
6. Contents of the pack and other information

1. WHAT ALLOPURINOL TABLETS ARE AND WHAT THEY ARE USED FOR

Allopurinol is used in adults to treat conditions caused by too much uric acid in your body such as:

- Gout (swelling of the joints caused by build-up of uric acid)
- Gouty Arthritis (a form of arthritis caused by deposits of uric acid)
- Skin Tophi (deposit of urates in the skin leaving lumps beneath the skin)
- Treatment and prevention of calcium renal lithiasis (kidney stones)
- During cancer chemotherapy to prevent uric acid build up.

In children, Allopurinol is used to treat:

- Leukaemia
- Enzyme disorders.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALLOPURINOL TABLETS

Do not take Allopurinol Tablets if you are:

- Allergic to allopurinol or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or pharmacist before taking allopurinol.

Warnings and precautions

Talk to your doctor before taking Allopurinol Tablets:

- If you are of Han Chinese, African or Indian origin
- If you have problems with your liver or kidneys. Your doctor may give you a lower dose or ask you to take it less often each day. They will also monitor you closely
- If you have heart problems or high blood pressure and you take diuretics and/or medicines called ACE-inhibitors
- If you are currently having an attack of gout
- If you have thyroid problems.

Serious skin rashes (hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) 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 cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to be sure to drink sufficiently to dilute your urine.

In case you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.

Children

Use in children is rarely indicated, except in some types of cancer (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

Other medicines and Allopurinol Tablets

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. In particular, any of the following medicines as your dose of Allopurinol Tablets may need to be adjusted:

- Aspirin
- Theophylline, used for breathing problems
- Medicines used for fits (epilepsy), phenytoin and carbamazepine
- Vidarabine, used to treat herpes and chickenpox
- Antibiotics (ampicillin or amoxicillin)
- Didanosine, used to treat HIV infection
- Medicines used for cancer e.g. azathioprine, mercaptopurine, cyclophosphamide, capecitabine
- Medicines used to reduce your immune response (immunosuppressants) e.g. ciclosporin
- Medicines used to treat diabetes e.g. chlorpropamide
- Medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics)
- Medicines used to thin your blood (anticoagulants), such as warfarin
- Any other medicine to treat gout.

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.

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.

Allopurinol Tablets with food and drink

Taking your tablets after food can help reduce side effects such as nausea and vomiting.

Pregnancy and breast-feeding

Allopurinol should only be taken during pregnancy if your doctor has said it is necessary.

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

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.

Driving and using machines

Allopurinol Tablets may cause tiredness, visual disturbances, dizziness and co-ordination disturbances; do not drive or use machinery if you are affected.

Allopurinol Tablets contain lactose

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

Allopurinol Tablets 300 mg contain sodium

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

3. HOW TO TAKE ALLOPURINOL TABLETS

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

Adults

You doctor will usually start with a low dose of Allopurinol Tablets (e.g. 100 mg/day), to reduce the risk of possible side effects. Your dose will be increased if necessary.

Doses above 300mg should be taken in divided doses. If you are elderly or if you have reduced liver or kidney

Dimension : 170 x 250 mm

Front Side

ARTWORK DETAIL LABEL

Product	Allopurinol Tab 100 & 300mg		
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert
Dimension	170 x 250 mm	Pack	----
New Item Code	1047063	Old Item Code	1046553
Colour Shades	■ BLACK	No. of Colours	1
Change Control No.	PC-TSG/2022/046 - Record Number: 333148		Artwork Version 9.0
Design/Style	Front & Back Side printing. To be supplied in the Unfolded size.		
Substrate	60 GSM Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.		
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.			

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

Use in children (under 15 years)

The usual dose is 10-20mg/kg bodyweight/day.

If you take more Allopurinol Tablets than you should

If you (or anyone else, including a child), take more Allopurinol Tablets than you should, contact a doctor or go to hospital straight away. Take the medicine pack with you. Signs of an overdose may include nausea, vomiting, diarrhoea and dizziness.

If you forget to take Allopurinol Tablets

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose.

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

If you stop taking Allopurinol Tablets

Do not stop taking your Allopurinol Tablets without talking to your doctor.

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

4. POSSIBLE SIDE EFFECTS

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

The following side effects may happen with this medicine:

Allergic reactions

Uncommon: (may affect up to 1 in 100 people)

If you have an allergic (hypersensitivity) reaction, stop taking Allopurinol Tablets and see a doctor straight away. The signs may include:

- Flaking skin, boils or sore lips and mouth
- Very rarely signs may include sudden wheeziness, fluttering or tightness in the chest and collapse.

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

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

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

Other side effects

Common: (may affect up to 1 in 10 people)

- Skin rash
- Increased level of thyroid stimulating hormone in the blood.

Uncommon: (may affect up to 1 in 100 people)

- Feeling sick (nausea) or being sick (vomiting)
- Abnormal liver tests.
- Diarrhoea

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

- Liver problems such as liver inflammation.

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

- Occasionally Allopurinol Tablets 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
- Allopurinol Tablets may affect the lymph nodes
- High temperature
- Blood in your urine (haematuria)
- High levels of cholesterol in your blood (hyperlipidaemia)
- A general feeling of being unwell or feeling weak
- Weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness

- Headache, dizziness, drowsiness or disturbance of your vision
- Chest pain (angina), high blood pressure or slow pulse
- Male infertility or erectile dysfunction
- Enlargement of the breasts, in men as well as women
- Vomiting blood
- Greasy stools
- A change in your normal bowel habit
- A change in taste
- Cataracts
- Hair loss or discolouration
- Depression
- Lack of voluntary coordination of muscle movements (ataxia)
- Sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- Build-up of fluid leading to swelling (oedema) particularly of your ankles
- Abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to check if this is happening
- Increased urea, creatinine or other nitrogen-containing compounds in the blood (azotaemia).

Not known: (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.

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 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.

5. HOW TO STORE ALLOPURINOL TABLETS

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in a dry place.

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 use this medicine if you notice any visible signs of deterioration.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Allopurinol Tablets contains

The active substance is allopurinol.

The other ingredients are:

100mg: Lactose (see section 2), maize starch, povidone, stearic acid.

300mg: Lactose (see section 2), maize starch, povidone, stearic acid, sodium starch glycollate.

What Allopurinol Tablets look like and contents of the pack

Allopurinol 100 mg tablets: white, biconvex tablet, embossed with 'AP' and '100' separated by a break line on one side and plain on other side.

Allopurinol 300 mg tablets: white, biconvex tablet, embossed with 'AP' and '300' separated by a break-line on one side and plain on the other side.

Polypropylene tablet container and cap
Pack sizes: 21, 100, 250, 500 and 1000 tablets.

Aluminium/PVC blister strips enclosed in outer carton
Pack sizes: 28 and 56 tablets.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.

Unit 4, Metro Centre,
Tolpits Lane, Watford,
Hertfordshire, WD18 9SS

This leaflet was last revised in 04/2022.



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Back Side

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