

Package leaflet: Information for the patient

Allopurinol Clonmel 100 mg tablets

Allopurinol Clonmel 200 mg tablets

Allopurinol Clonmel 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 Clonmel is and what it is used for
2. What you need to know before you take Allopurinol Clonmel
3. How to take Allopurinol Clonmel
4. Possible side effects
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1. What Allopurinol Clonmel is and what it is used for

Allopurinol Clonmel contains the active substance allopurinol. This medicine belongs to a group of medicines called enzyme inhibitors, which control the speed at which certain chemical changes occur in your body.

Allopurinol Clonmel is used in adults, adolescents and children to treat conditions where too much uric acid is produced by your body such as: gout, certain types of kidney disease and kidney stones, cancer and some enzyme disorders which lead to the build-up of too much uric acid.

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

DO NOT take Allopurinol Clonmel

- if you are allergic to allopurinol or any of the other ingredients of this medicine (listed in section 6)
- If you are not sure, check with your doctor before taking the medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Allopurinol Clonmel if you:

- are suffering, or have you suffered, from liver or kidney disease
- are taking medicines (diuretics and/or a medicine called ACE inhibitors) for heart disease or high blood pressure
- are experiencing an acute attack of gout
- are of Han Chinese, Thai or Korean origin
- have thyroid problems

Take special care with Allopurinol Clonmel

- if you have kidney stones. The kidney stones will become smaller and have a chance of entering and blocking your urinary tract

- as serious skin rashes (hypersensitivity syndrome, Stevens- Johnson syndrome, toxic epidermal necrolysis) have been reported in patients taking 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 flu-like symptoms such as fever, headache, body ache. The rash may progress to widespread blistering and peeling of the skin.
These serious skin reactions are more common in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients. 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 in your urine may increase. To prevent this, you need to drink plenty of fluids so that your urine is diluted

Children and adolescents

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

Other medicines and Allopurinol Clonmel

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

- medicines used to reduce your immune response (immunosuppressants) e.g. **6-mercaptopurine, azathioprine and cyclosporin**
The co-administration of 6-mercaptopurine or azathioprine with allopurinol should be avoided. When 6-mercaptopurine or azathioprine is given concurrently with Allopurinol Clonmel, 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.
Seek medical advice immediately if you notice that you have any unexplained bruising, bleeding, fever or sore throat.
- **adenine arabinoside (vidarabine)**, used to treat herpes or chickenpox
- other medicines to treat gout, such as **probenecid**
- **acetylsalicylic acid** (or related medicines called salicylates)
- **chlorpropamide**, used to treat diabetes
- medicines which thin the blood (anticoagulants), such as **warfarin**
- medicines used for fits (epilepsy), **phenytoin**
- **theophylline**, used for breathing problems
- antibiotics (**ampicillin** or **amoxicillin**)
- medicines used for the treatment of cancer
- **didanosine**, used to treat HIV infection
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics)
- **aluminium hydroxide**, as it may reduce the effect of allopurinol. There should be an interval of at least 3 hours between taking both medicines
- when taking Allopurinol Clonmel and cytotoxic medicines (e.g. **cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides**), blood disorders occur more frequently than when these active substances are administered by themselves
Blood count monitoring should therefore be performed at regular intervals.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Allopurinol Clonmel should only be used during pregnancy if no safer alternative exists and if the disease itself poses a risk to the mother and the unborn child.

Allopurinol is passed into human breast milk. Taking allopurinol during breast-feeding is not recommended.

Driving and using machines

Allopurinol may make some people drowsy or have problems with their coordination. Do not drive or operate machinery until you know how it affects you.

Allopurinol Clonmel contains 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 Clonmel 300 mg tablets contain the colouring agent sunset yellow

Sunset yellow may cause allergic reactions.

3. How to take Allopurinol Clonmel

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

Dose

The amount of allopurinol that people can take varies from person to person. Your doctor will decide on a dose of Allopurinol Clonmel that is right for you.

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.

Adults

Starting dose - 100 to 300 mg daily, which may be taken as a single dose, after a meal.

Maximum dose - 900 mg daily, depending on the severity of your condition.

If you are taking a daily dose higher than 300 mg, your doctor may tell you to divide the total dose into smaller doses spaced evenly throughout the day to reduce the risk of gastrointestinal side effects.

Kidney or liver problems

If you are an older person or if you have reduced liver or kidney function, your doctor may prescribe a lower dose or taking it at longer intervals. 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.

Children and adolescents under 15 years

10 to 20 mg per kg up to a maximum of 400 mg daily divided into three doses. Use in children is rare, except in malignant conditions (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

Method of administration

Allopurinol Clonmel is for oral use.

The tablets should be taken with a glass of water and after a meal to reduce the risk of side effects such as nausea (feeling sick) and vomiting.

If you take more Allopurinol Clonmel than you should

If you take too many tablets or someone else takes your medicine by mistake, tell your doctor at once or go to the 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 Clonmel

If you forget to take a dose, take another one as soon as you remember. However, if it is nearly 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 Clonmel

Do not stop taking Allopurinol Clonmel unless your doctor tells you to.

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.

Serious allergic reaction

Uncommon (may affect up to 1 in 100 people)

Check with your doctor **immediately** if you experience any of the following:

- a reaction of any kind such as flaking skin, boils or sore lips and mouth
- or very rarely, sudden wheeziness, fluttering or tightness in the chest; 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, 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 and conjunctivitis (red and swollen eyes), widespread blisters or peeling

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

These symptoms may mean that you are allergic to allopurinol. **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)

- 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 visual disturbance
- chest pain (angina), high blood pressure or a slow pulse
- fluid retention leading to swelling (oedema) particularly of the ankles
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of glucose in your blood to help to decide if this is happening

- 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 if this happens
- allopurinol may affect the lymph nodes
- male infertility, impotence
- enlargement of the breasts, in men as well as women
- a change in your normal bowel habits
- change in sense of taste
- eye problems such as clouding of the lens (cataracts)
- hair loss or discolouration
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)

Not known (frequency cannot be estimated from the available data)

- aseptic meningitis (inflammation of the membranes that surround the brain and spinal cord): symptoms include neck stiffness, headache, nausea, fever or clouded consciousness. Seek medical attention immediately if these occur
- lichenoid skin rash (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes)

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:

Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie

Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allopurinol Clonmel

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 the blister after EXP. The expiry date refers to the last day of that month.

This medicine 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.

6. Contents of the pack and other information

What Allopurinol Clonmel contains

The active substance is allopurinol.

Each tablet contains 100 mg allopurinol.

Each tablet contains 200 mg allopurinol.

Each tablet contains 300 mg allopurinol.

The other ingredients are: maize starch, pregelatinised; lactose monohydrate; crospovidone; povidone; silica, colloidal anhydrous; magnesium stearate

Additionally, for Allopurinol Clonmel 300 mg tablets

FD&C Yellow no. 6-aluminium lake (LAKE PIGMENT HT) E110

What Allopurinol Clonmel looks like and contents of the pack

Allopurinol Clonmel 100 mg tablets

White to off-white, flat faced bevelled edged, round tablet, debossed with “0” and "21" on either side of break line and "100" on the other side.

The tablet can be divided into equal doses.

Allopurinol Clonmel 200 mg tablets

White to off-white, biconvex, round tablet, debossed with “B2” on one side.

Allopurinol Clonmel 300 mg tablets

Peach coloured, flat faced bevelled edged, round tablet, debossed with “300” and “020” on either side of break line.

The tablet can be divided into equal doses.

Allopurinol Clonmel 100 mg tablets

PVC/Alu blister containing 20, 25, 28, 30, 50, 60, 90 and 100 tablets.

Allopurinol Clonmel 200 mg tablets

PVC/Alu blister containing 28, 30, 90 and 100 tablets.

Allopurinol Clonmel 300 mg tablets

PVC/Alu blister containing 20, 28, 30, 50, 60, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Laboratori Fundació Dau, C/C, 12-14 Pol. Ind., Zona Franca, 08040 Barcelona, Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Germany:	Allopurinol AL 100 mg, 200 mg, 300 mg Tabletten
Belgium:	Allopurinol Eurogenerics 100 mg, 200 mg, 300 mg tabletten
France:	Allopurinol EG LABO 100 mg, 300 mg, comprimé sécable, Allopurinol EG LABO 200 mg, comprimé
Ireland:	Allopurinol Clonmel 100 mg, 200 mg, 300 mg tablets
Austria:	Allopurinol !Stada 100 mg, 200 mg, 300 mg Tabletten
Spain:	Alopurinol STADAFARMA 100 mg, 200 mg, 300 mg comprimidos EFG
Portugal:	Alopurinol Ciclum Farma 100 mg, 200 mg, 300 mg comprimidos
Luxembourg:	Allopurinol Eurogenerics 100 mg, 200 mg, 300 mg comprimés
Malta:	Allopurinol Clonmel 100 mg, 200 mg, 300 mg tablets
Czech Republic:	Alopurinol STADA 100 mg, 200 mg, 300 mg tablety
The Netherlands:	Allopurinol CF 100 mg, 200 mg, 300 mg, tabletten
Norway:	Allopurinol STADA 100 mg, 200 mg, 300 mg tablett
Finland:	Allopurinol STADA 100 mg, 200 mg, 300 mg tabletti
Slovakia:	Alopurinol STADA 100 mg, 200 mg, 300 mg tablety
Romania:	Alopurinol Stada 100 mg, 200 mg, 300 mg comprimate

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