

Package leaflet: Information for the user

Tipuric 100mg Tablets Tipuric 300mg 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. 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 Tipuric tablets are and what they are used for
2. What you need to know before you take Tipuric tablets
3. How to take Tipuric tablets
4. Possible side effects
5. How to store Tipuric tablets
6. Contents of the pack and other information

1. What Tipuric tablets are and what they are used for

Allopurinol, the active ingredient in these tablets belongs to a group of medicines called enzyme inhibitors. It controls the amount of uric acid in the body.

Tipuric tablets are used to prevent gout and other conditions associated with excess uric acid in the body, including kidney stones and certain types of kidney disease. Tipuric tablets should not be used to treat a sudden attack of gout.

2. What you need to know before you take Tipuric tablets

Do not take Tipuric tablets

- if you are allergic (hypersensitive) to allopurinol or any of the other ingredients of Tipuric tablets (see section 6.)
- if you are breast-feeding
- if you are having an attack of gout at the moment.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tipuric tablets

- if you suffer from a kidney or liver disorder
- if you are taking medicines for heart disease or high blood pressure
- if you are pregnant or planning to become pregnant

It is important to **drink plenty of water** while you are taking these tablets.

There is a **possibility that kidney stones may become impacted** in the ureter (the tube that runs from the kidney to the bladder) during treatment with this medicine.

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.

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 Tipuric, you must not be restarted on Tipuric at any time.

Other medicines and Tipuric tablets

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

- 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 Tipuric tablets are taken at the same time as: aspirin (or related drugs called salicylates)
- theophylline, which is used to help your breathing
- antibiotics (e.g. ampicillin or amoxicillin)
- drugs used to treat epilepsy (e.g. phenytoin)
- drugs used to treat cancer (e.g. cyclophosphamide, doxorubicin, bleomycin and procarbazine)
- drugs used to reduce the immune response (e.g. azathioprine, ciclosporin)
- drugs used to treat diabetes (e.g. chlorpropamide)
- drugs used to thin the blood (anticoagulants) such as warfarin
- any other drugs used to treat gout (e.g. probenecid)
- drugs used in the treatment of leukaemia (e.g. 6-mercaptopurine)
- vidarabine, an antiviral drug used to treat herpes simplex
- didanosine, an antiretroviral drug used to treat HIV patients.
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics).
- 6-mercaptopurine (used to treat blood cancer)
- azathioprine (used to suppress the immune system)

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.

The co-administration of 6-mercaptopurine or azathioprine with allopurinol should be avoided. When 6-mercaptopurine or azathioprine is given concurrently with Tipuric tablets, 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.

Tipuric tablets with food and drink

Tipuric tablets should be taken with a drink of water after food.

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

Driving and using machines

As this medicine may cause drowsiness, giddiness and affect your coordination, you should not drive or operate machinery until you know how this drug affects you.

Tipuric 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.

3. How to take Tipuric tablets

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 recommended doses are as follows:

Adults

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.

The recommended starting dose is in the range of 100 mg – 300 mg daily, which may be taken as a single dose, after a meal. The tablets should be taken with a glass of water. The dose may be increased up to 900 mg daily, depending on the severity of your condition.

Doses higher than 300 mg should be given in divided doses not exceeding 300 mg at any one time.

Elderly

Your doctor will prescribe the lowest dose that best controls your symptoms.

Use in children and adolescents under 15 years

The recommended dose is in the range 100 mg – 400 mg daily.

Hepatic impairment

Your doctor will prescribe the lowest dose that best controls your symptoms. Your doctor will arrange for you to have liver function tests during the early stages of your treatment.

Renal impairment

Your doctor will prescribe the lowest dose that best controls your symptoms. If you have serious kidney problems, your doctor may prescribe less than 100 mg per day or tell you to take a single dose of 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 mg – 400 mg which is to be taken straight after dialysis.

You should visit your doctor regularly if you are taking this medicine on a long term basis.

If you take more Tipuric tablets than you should

An occasional unintentional extra dose is unlikely to cause problems, however, if you or anyone else has taken a lot of the tablets together you should contact your nearest hospital casualty department or your doctor immediately.

If you forget to take Tipuric tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time to take the next one then go on as before. Do not take a double dose to make up for a forgotten dose.

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.

You may experience an attack of gout (reactive gout) when you start treatment with Tipuric tablets.

If you experience any of the following **STOP** taking the tablets and tell your doctor **as soon as possible**:

- high temperature
- joint pain or painful swelling of the groin, armpits or neck

- jaundice (yellowing of the skin and eyes)
- nausea and vomiting (in some cases blood may be present)
- a general feeling of being unwell
- weakness
- numbness
- loss of consciousness
- headache
- dizziness
- drowsiness
- disturbance of vision
- chest pain
- high blood pressure
- a slow pulse
- retention of fluid leading to swelling (oedema) particularly of the ankles
- feeling thirsty, tired and losing weight; these may be symptoms of diabetes. Your doctor may measure the level of sugar in your blood to check for diabetes.

If you experience any of the following, stop your tablets and tell your doctor immediately:

Common: may affect up to 1 in 10 people

- Increased level of thyroid stimulating hormone in the blood.

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

- Sudden wheeziness, fluttering or tightness in the chest; collapse.
- 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.
- 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

- 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.
- 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 ONE OF THE INGREDIENTS IN THESE TABLETS. Do **not** take any more tablets unless your doctor tells you to do so.

Occasionally, Tipuric tablets may affect your blood or lymphatic system. These effects have usually occurred in people with liver or kidney problems. However, you should 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**.

Side effects listed below have been reported in the following frequencies:

Uncommon: may affect up to 1 in 100 people

- Diarrhoea

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

- Tipuric tablets may affect your liver or kidney function.

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

- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).
- infertility
- impotence
- enlargement of the breast – in men as well as women
- a change in your normal bowel habit
- change in taste perception
- cataracts
- hair loss or discolouration
- convulsions
- fits
- depression.

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.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: 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 Tipuric Tablets

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

Do not store above 25°C.

Keep the container tightly closed.

Store in the original container.

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 Tipuric tablets contain

- The active substance is allopurinol. The tablets contain either 100 mg allopurinol or 300 mg allopurinol.
- The other ingredients are lactose monohydrate, maize starch, povidone, crospovidone and magnesium stearate.

What Tipuric tablets look like and contents of pack

Tipuric 100 mg Tablets: White, circular tablets with '230' and a breakline on one side and the company logo on the reverse.

Tipuric 300 mg Tablets: White, circular tablets with '242' and a breakline on one side and the company logo on the reverse.

Pack sizes

Tipuric 100 mg Tablets: 30, 40, 50, 100, 250 and 500 tablets

Tipuric 300 mg Tablets: 40, 50, 100, 250, 500 and 1,000 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer

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

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