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Ennogen Pharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Uricto 100mg and 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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

Uricto Tablets contain a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body.

Uricto Tablets are used:-

- To prevent gout. This is a disease where your body produces too much of a substance called 'uric acid'. The uric acid builds up in your joints and tendons and forms crystals. These cause an inflammatory reaction. The inflammation causes the skin around certain joints to become swollen, tender and sore when only slightly touched. Severe pain may also be felt on slight movement of the joint.
- To prevent other conditions where there is a build up of uric acid in the body. This includes kidney stones.

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

Do not take Uricto Tablets if you:

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

Warnings and precautions

Talk to your doctor, or pharmacist or nurse before taking Uricto Tablets if you:

- Have liver or kidney problems. Your doctor may give you a lower dose or ask you to take it less often each day. You will also be monitored more closely.
- Have heart problems or high blood pressure and you take diuretics and/or a medicine called ACE inhibitors
- Have been told by your doctor that you have an intolerance to some sugars as this medicine contains lactose
- Are currently having an attack of gout
- You have thyroid problems
- You are of Han Chinese, African or Indian origin.

Serious skin rashes (hypersensitivity syndrome, Stevens- Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Uricto Tablets.

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 Uricto Tablets 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.

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

Children and adolescents

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 Uricto Tablets

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

In particular tell your doctor if you are taking any of the following:

- Azathioprine (to treat rheumatoid arthritis and after organ transplants)
- Ciclosporin (to treat psoriasis, rheumatoid arthritis or after organ transplants)
- 6-mercaptopurine (used to treat some cancers and bowel diseases)
- Cyclophosphamide, doxorubicin, bleomycin or procarbazine (drugs used to treat leukaemias and some cancers)
- Probenecid (used in gout)
- Phenytoin (used in epilepsy)
- Theophylline (to treat asthma)
- Ampicillin or amoxicillin (antibiotics)
- Aspirin or related medicines (salicylates)
- Drugs to prevent blood from clotting (such as warfarin)
- Chlorpropamide (used in diabetes)
- Didanosine (antiviral)
- Diuretics (water tablets) or ACE inhibitors such as captopril (used in high blood pressure)
- Vidarabine, used to treat herpes or chickenpox.

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.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice if you are pregnant, planning on becoming pregnant or are breast-feeding. Please check with your doctor if you are taking these tablets and want to breast-feed your baby. Allopurinol is excreted in the human breast milk. Allopurinol during breastfeeding is not recommended.

Driving and using machines

These tablets can cause some people to feel drowsy, giddy or have problems with co-ordination. If you are affected do not drive or operate machinery as your alertness may be impaired.

Uricto Tablets contain lactose

Uricto 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 medicinal product.

3. HOW TO TAKE URICTO TABLETS

Always take Uricto Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

Swallow the tablet with a drink of water

Take with or just after food.

Adults:

The usual starting dose is 100 to 200mg each day. Your doctor will monitor the uric acid levels in your blood or urine at regular intervals and will adjust the dose to suit you as necessary. The maintenance dose is usually 200mg to 600mg daily. The maximum single dose is 300mg. It is

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unlikely that you will be prescribed more than 900mg per day.

Use in children and adolescents:

The dose in children is based on 10mg to 20mg/kg of body weight/day. Your doctor will prescribe the correct dosage. Use in children is mainly for certain types of cancers and enzyme disorders.

Elderly patients:

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

Patients with severe kidney problems:

You may be asked to take less than 100mg a day, or you may be asked to take 100mg at a longer interval than each day. The exact dose will be prescribed by your doctor.

If you are receiving kidney dialysis two or three times a week, your doctor may prescribe a dose of 300 or 400mg which will be to take straight away after your dialysis.

Patients with liver problems:

A reduced dose will be prescribed by your doctor.

If you take more Uricto Tablets than you should

If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you.

If you stop taking Uricto Tablets

Do not stop taking Uricto Tablets without consulting your doctor.

If you forget to take Allopurinol Tablets

If you have forgotten to take a dose, take it as soon as you remember it. However, if it is almost time to take your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. If you have trouble remembering to take the tablets, tell your doctor or pharmacist.

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

4. POSSIBLE SIDE EFFECTS

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

The following side effects may happen with this medicine:

Hypersensitivity

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

If you have a hypersensitivity reaction, stop taking Uricto 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):

- serious hypersensitivity reactions including
 - ▶ fever, joint pain, abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder)
 - ▶ 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.

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 or being sick (occasionally with blood)
- changes in liver function tests.

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 Uricto 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.
- Uricto Tablets may affect the Lymph Nodes
- weakness, numbness, 'pins and needles',

'spinning' sensation, unable to move muscles (paralysis), drowsiness, loss of consciousness

- feeling thirsty, tired and losing weight; these may be signs of diabetes, taste changes, build up of fluid leading to swelling (oedema) particularly of your ankles
- high levels of cholesterol in the blood (hyperlipidaemia)
- depression
- hair loss or discolouration
- cataracts, changes in vision
- blood in the urine (haematuria), a change in bowel habit
- high temperature, a general feeling of being unwell, headache, dizziness
- high blood pressure
- enlarged breasts in men and women, difficulty maintaining erection, infertility
- chest pain (angina) or slow pulse
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, prickling or burning skin (paraesthesia)
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to check 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 as soon as possible.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 URICTO 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. The expiry date refers to the last day of that month.

Blister packs: Do not store above 25°C. Keep the blister in the outer carton to protect from light and moisture.

Securainers: Store in a cool, dry place and protect from light.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Uricto Tablets contain:

Uricto Tablets 100mg and 300mg contain the active substance Allopurinol 100mg and 300mg respectively in each tablet.

The other ingredients are: lactose, maize starch, povidone, magnesium stearate and sodium starch glycolate.

What Uricto Tablets look like and contents of the pack

Uricto Tablets 100mg are white, circular biconvex, uncoated tablets, with A1 embossed on one side. Diameter: 9.5mm.

Uricto Tablets 300mg are white, circular, biconvex, uncoated tablets, with 'A' & '2' debossed on either side of score line on one side and plain on other side. Diameter: 11.00mm.

Uricto Tablets 100mg are supplied in packs of 28, 30, 56, 60, 84, 90 or 250 tablets.

Uricto Tablets 300mg are packed into packs of 28, 30, 56, 60, 84, 90 or 250 tablets.

Marketing Authorisation Holder and Manufacturer

Ennogen Pharma Limited
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK.

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