

Package Leaflet: Information for the User
Tioguanine 40 mg tablets
tioguanine

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, nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Tioguanine is and what it is used for

Tioguanine tablets contain a medicine called tioguanine. This belongs to a group of medicines called cytotoxics (also called chemotherapy). Tioguanine is used for certain blood problems and cancers of the blood. It works by reducing the number of new blood cells your body makes.

Tioguanine is used for acute (fast-growing) leukaemias, especially:

- **Acute myelogenous leukaemia** (also called **acute myeloid leukaemia** or **AML**) - a fast-growing disease that increases the number of white blood cells produced by the bone marrow. This can cause infections and bleeding.
- **Acute lymphoblastic leukaemia** (also called **acute lymphocytic leukaemia** or **ALL**) - a fast-growing disease which increases the number of immature white blood cells. These immature white blood cells are unable to grow and function properly and therefore cannot fight infections and may cause bleeding.

Ask your doctor if you would like more explanation about these diseases.

2. What you need to know before you take Tioguanine

Do not take Tioguanine:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Tioguanine:

- if you have been taking this medicine for a long period of time. This may increase the chance of side effects, such as liver problems
- if you have a condition where your body produces too little of something called TPMT or 'thiopurine methyltransferase'
- if you have 'Lesch-Nyhan Syndrome'. This is a rare condition that runs in families caused by a lack of something called HPRT or 'hypoxanthine-guanine-phosphoribosyltransferase'.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking Tioguanine.

NUDT15-gene mutation

If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of Tioguanine in the body), you have a higher risk of infections and hair loss and your doctor may in this case give you a lower dose. Your doctor may also perform genetic testing (i.e. looking at your TPMT and/or NUDT15 genes) before or during your treatment to determine if your response to this medication may be affected by your genetics. Your doctor may change your dose of Tioguanine after these tests.

Tioguanine and the sun

While taking Tioguanine you may become sensitive to the sunlight which can cause skin discolouration or a rash. Take care to avoid too much sun, cover up and use sunscreen.

Other medicines and Tioguanine

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

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

- olsalazine or mesalazine – used for a bowel problem called ulcerative colitis.
- sulfasalazine – used for rheumatoid arthritis or ulcerative colitis.
- medicines that can have a harmful effect on the bone marrow, like other chemotherapy or radiotherapy. This can lead to bone marrow damage and the dose of Tioguanine may need to be reduced.

Having vaccines while you are taking Tioguanine

If you are going to have a vaccination speak to your doctor or nurse before you have it. This is because some vaccines (like polio, measles, mumps and rubella) may give you an infection if you have them whilst you are taking Tioguanine.

Pregnancy, breast-feeding and fertility

If you are pregnant or are planning to have a baby, ask your doctor for advice before you take Tioguanine. This applies to both men and women. Tioguanine may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are taking these tablets. If you are breast-feeding, ask your doctor or midwife for advice before taking Tioguanine.

Tioguanine 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 Tioguanine

Tioguanine should only be given to you by a specialist doctor who is experienced in treating blood problems.

Always take this medicine exactly as your doctor has told you. It is important to take your medicine at the right times. The label on your pack will tell you how many tablets to take and how often to take them. Check with your doctor, pharmacist or nurse if you are not sure.

- Swallow your tablets whole with a glass of water.
- If you need to break your tablet in half, do not inhale any tablet powder. Wash your hands afterwards. The scoreline is only there to help you break the tablet if you have difficulty swallowing it whole.
- When you take Tioguanine your doctor will take regular blood tests. This is to check the number and type of cells in your blood and to ensure your liver is working correctly. Your doctor may sometimes change your dose as a result.

The dose of Tioguanine you are given will be worked out by your doctor based on:

- your body size (surface area).
- the results of your blood test.

- the disease being treated.
- The recommended dose is between 100 and 200 mg/m² body surface area per day. If you have a problem with your kidneys or liver you may be given a lower dose of Tioguanine.

If you take more Tioguanine than you should

If you take more Tioguanine than you should, tell your doctor immediately or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Tioguanine

Tell your doctor. **Do not take a double dose to make up for a forgotten dose.**

4. Possible side effects

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

If you get any of the following, talk to your specialist doctor or go to hospital straight away:

- any signs of fever or infection (sore throat, sore mouth or urinary problems).
- any **unexpected** bruising or bleeding, as this could mean that too few blood cells of a particular type are being produced.
- if you **suddenly** feel unwell (even with a normal temperature).
- any yellowing of the whites of the eyes or skin (jaundice).

Talk to your doctor if you have any of the following side effects which may also happen with this medicine:

Very common (may affect more than 1 in 10 people)

- a drop in the number of your blood cells and platelets.
- jaundice (skin and the whites of the eyes turn yellow) and severe liver damage (symptoms include fatigue and nausea followed by pruritus, dark urine and may include rash or fever) - with long term use or high doses of Tioguanine – this may also show up in your blood tests.

Common (may affect up to 1 in 10 people)

- liver damage which can cause jaundice (skin and the whites of the eyes turn yellow) or an enlarged liver (a swelling below your ribcage) – with short term use of Tioguanine – this may also show up in your blood tests.
- feeling or being sick (nausea or vomiting), diarrhoea and mouth ulcers.
- Increased uric acid concentrations in the blood (hyperuricaemia), which can sometimes lead to decreased kidney function.

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

- a problem with your bowels, called necrotising colitis, which can cause severe stomach ache, being sick, diarrhoea, vomiting and fever.
- severe liver damage when used with other chemotherapy drugs, oral contraceptives and alcohol.

Not known: frequency cannot be estimated from the available data

- Sensitivity to light.

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

5. How to store Tioguanine

- 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 pack after 'Exp'.
- Do not store your Tioguanine tablets above 25°C. Keep dry and protect from light.
- If your doctor tells you to stop taking the tablets, it is important to return any which are left over to your pharmacist, who will destroy them according to disposal of dangerous substance guidelines. Only keep the tablets if your doctor tells you to.

6. Contents of the pack and other information

What Tioguanine contains

The active substance is Tioguanine. Each Tioguanine tablet contains 40 mg of tioguanine. The other ingredients are lactose monohydrate, starch (potato), acacia, stearic acid, magnesium stearate and purified water.

What Tioguanine looks like and contents of the pack

Tioguanine tablets are white to off-white tablets, round, biconvex scored and imprinting 'T40' on upper side, without score and debossing on lower side. Your Tioguanine tablets are in bottles of 25 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder:
Aspen Pharma Trading Limited
3016 Lake Drive,
Citywest Business Campus,
Dublin 24
Ireland

Manufacturer:
EXCELLA GmbH & Co. KG, Nürnberger Strasse 12, 90537 Feucht, Germany

Medical information enquires:

For any Medical Information enquiries about this product, please contact: 24 Hour Helpline +44 1748 828 391 (free phone UK only 0800 0087 392)

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Tioguanine 40mg tablets**

Reference number PL 39699/ 0045

This is a service provided by the Royal National Institute of Blind People.

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