

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hanixol 50 mg Tablets

6-mercaptopurine

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

What is in this leaflet

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1. What Hanixol 50 mg Tablets are and what they are used for

Hanixol 50 mg Tablets contain a medicine called 6-mercaptopurine.

This belongs to a group of medicines called cytotoxics (also called chemotherapy). Hanixol 50 mg Tablets are used to treat cancer of the blood (leukaemia) in adults, adolescents and children. It works by reducing the number of new blood cells your body makes.

2. What you need to know before you take Hanixol 50 mg Tablets

Do not take Hanixol 50 mg Tablets:

If you are allergic to 6-mercaptopurine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Hanixol 50 mg Tablets:

- If you have recently received, or are due to receive, a vaccination (vaccine). If you take Hanixol, you should not have a live organism vaccine (for example; flu vaccine, measles vaccine, BCG vaccine, etc.) until advised it is safe to do so by your doctor. This is because some vaccines may give you an infection if you receive them while you are taking Hanixol
- If you have a genetic disease called TPMT (thiopurine methyltransferase) deficiency.
- If you are allergic to a medicine called azathioprine (also used to treat cancer).
- If you have reduced liver function or liver damage.
- If you have a genetic disease called Lesch-Nyhan syndrome.
- If you have a kidney problem.
- Tell your doctor whether you have, or have not, had chicken pox, shingles or hepatitis B (a liver disease caused by a virus).
- If you are pregnant or breast-feeding. If you are male, please note the risk of teratogenic effect.
- If you are taking at the same time allopurinol.

- If you are taking at the same time warfarin or other drugs that may have blood thinning effect (e.g. aminosalicic acid).
- If you have any intolerance to lactose.

If you are receiving immunosuppressive therapy, taking Hanixol 50 mg Tablets could put you at greater risk of:

- Tumours, including skin cancer. Therefore, when taking Hanixol 50 mg Tablets, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- Lymphoproliferative disorders:
 - treatment with Hanixol 50 mg Tablets increases your risk of getting a type of cancer called lymphoproliferative disorder. With treatment regimen containing multiple immunosuppressants (including thiopurines), this may lead to death.
 - a combination of multiple immunosuppressants, given concomitantly increases the risk of disorders of the lymph system due to a viral infection (Epstein-Barr virus (EBV)- associated lymphoproliferative disorders).

Taking Hanixol 50 mg Tablets could put you at greater risk of:

- Developing a serious condition called Macrophage Activation Syndrome (excessive activation of white blood cells associated with inflammation), which usually occurs in people who have certain types of arthritis.

Blood tests

Hanixol 50 mg Tablets can affect your bone marrow. This means you may have a reduced number of white blood cells, platelets and (less commonly) red blood cells in your blood. Your doctor will take daily blood tests at the beginning of your treatment and at least once a week in your treatment (maintenance). This is to check the levels of these cells in your blood. If you stop treatment early enough, your blood cells will return to normal.

Other laboratory tests

- Additional laboratory tests (urine, blood, etc.) may also be carried out as directed by your doctor.

Hepatic function

Hanixol 50 mg Tablets are toxic to your liver. Therefore, your doctor will take regular blood tests when you are taking Hanixol. This is to check and to ensure your liver is working correctly.

If you notice the whites of your eyes or your skin turn yellow (jaundice) tell your doctor immediately as you may need to stop your treatment immediately

Infections

When you take Hanixol 50 mg Tablets you may be more prone to infections and your reaction to these infections may be more serious than people not being treated with Hanixol 50 mg Tablets. Tell your doctor immediately if you think you have an infection.

Sun and UV light

During your treatment with Hanixol 50 mg Tablets you are more sensitive to the sun and UV light. You must be sure to limit your exposure to sunlight and UV light, wear protective clothing and use sunscreen with a high SPF.

Children and adolescents

Low blood sugar levels (sweating more than usual, nausea, dizziness, confusion, etc.) have been reported in some children receiving Hanixol; however, most of the children were under the age of six years old and had a low body weight.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Hanixol 50 mg Tablets.

Other medicines and Hanixol 50 mg Tablets

Tell your doctor or pharmacist 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:

- Ribavirin (used to treat viral infections)
- Other cytotoxic drugs (used to treat cancer)
- Allopurinol thiopurinol, oxypurinol or febuxostat (used mainly to treat gout)
- Olsalazine (used to treat bowel problems called, ulcerative colitis)
- Mesalazine (used to treat bowel problems called Crohn's disease and ulcerative colitis)
- Sulfasalazine (used for rheumatoid arthritis or ulcerative colitis)
- Methotrexate (used to treat cancers, rheumatoid arthritis or severe psoriasis)
- Infliximab (used to treat bowel disorders Crohn's disease and ulcerative colitis), rheumatoid arthritis, inflammation of the spinal column (ankylosing spondylitis) or severe psoriasis
- Warfarin or acenocoumarol (anticoagulants).

Having vaccines while you are taking Hanixol 50 mg Tablets

If you are going to have a vaccination, speak to your doctor or nurse before you have it. This is because some live vaccines (like polio, measles, mumps and rubella) may give you an infection if you have them whilst you are taking Hanixol 50 mg Tablets.

Hanixol 50 mg tablets with food and drink

You can take Hanixol 50 mg Tablets with food or on an empty stomach, but the way you choose should be the same, day to day. You should take Hanixol 50 mg Tablets at least 1 hour before or 2 hours after ingestion of milk or dairy products.

Pregnancy, breast-feeding and fertility

Treatment with Hanixol 50 mg Tablets is not recommended during pregnancy, particularly in the first three months, because it may cause permanent damage to a foetus. If you think you could be pregnant, or if you are planning to become pregnant, check with your doctor before taking Hanixol 50 mg Tablets. Your doctor will consider the risks and benefits to you and your baby of taking Hanixol 50 mg Tablets.

Do not take Hanixol 50 mg Tablets if you are planning to have a baby. This applies to both men and women. Reliable contraceptive precautions must be taken to avoid pregnancy during treatment with Hanixol 50 mg Tablets and for at least 3 months afterwards.

Breastfeeding should not occur during treatment with Hanixol 50 mg Tablets as Hanixol has been detected in human milk.

Driving and using machines

It is not expected that Hanixol will affect your ability to drive or use machines, but no studies have been done to confirm this.

Hanixol 50 mg Tablets contain lactose.

If you have been told by your doctor that you have an intolerance to lactose, contact her/him before taking this medicine.

3. How to take Hanixol 50 mg Tablets

Hanixol 50 mg Tablets should only be given to you by a specialist doctor who is experienced in treating cancers of the blood.

- During treatment with Hanixol 50 mg Tablets, 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 also ask for other blood and urine tests to monitor how your kidneys are working and to measure your uric acid levels. Uric acid is a natural body chemical, levels of which can rise while taking Hanixol. High levels of uric acid may damage your kidneys.
- Your doctor may sometimes change your dose of Hanixol 50 mg Tablets as a result of these tests.

Always take Hanixol 50 mg Tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important that the Tablets are taken at the right time.

The recommended dose for adults and children is 2.5 mg per kilogram of body weight per day (or alternatively, 50 to 75 mg per square meter (m²) of body surface area per day). Your doctor will calculate and adjust your dose based on your weight, the results of your blood tests, if you take other chemotherapy drugs, as well as your kidney and liver function.

- Swallow the tablets whole with some water. The tablets should not be broken or crushed. You can take your medicine with food or on an empty stomach, but the way you choose should be the same day to day. You should take Hanixol 50 mg Tablets at least 1 hour before or 2 hours after ingestion of milk or dairy products

If you take more Hanixol 50 mg Tablets than you should

If you take too many Hanixol 50 mg Tablets or if someone else took your medication by mistake, immediately contact your doctor for advice or go to the nearest hospital. Take the medicine pack with you. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to take Hanixol 50 mg Tablets

If you forget to take a dose, inform your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Hanixol

If you stop taking Hanixol, tell your doctor immediately.

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

4. Possible side effects

Like all medicines, Hanixol 50 mg Tablets can cause side effects, although not everybody gets them. The side effects of Hanixol 50 mg Tablets relate to the pharmacological effects of 6-mercaptopurine

If you get any of the following, talk to your specialist doctor straight away or seek urgent medical advice:

- An allergic reaction with swelling of the face and sometimes mouth and throat (this is a very rare side effect).
- An allergic reaction with joint pain, skin rashes, high temperature (fever) (this is a rare side effect).
- Yellowing of the skin and whites of the eyes. If you get such symptoms, you should stop taking Hanixol.
- Any signs of a high temperature or infection (feeling very tired or unwell, sore throat, sore mouth or urinary problems) or any unexplained bruising or bleeding.

Treatment with Hanixol affects your bone marrow causing a reduction in your white blood cells and platelets (this is a very common side effect).

Therefore, your doctor will periodically take blood samples.

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

Common (may affect up to 1 in 10 people)

- Nausea or vomiting
- Anaemia

Uncommon (may affect up to 1 in 100 people)

- Loss of appetite

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

- Mouth ulcers
- Inflammation of the pancreas which may include abdominal pain, nausea or vomiting
- Severe damage to liver cells (hepatic necrosis)
- Hair Loss
- Various types of cancers including blood, lymph and skin cancers

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

- Blood cancer (Leukaemia)
- Cancer of the liver and spleen (in patients with a disease called inflammatory bowel disease)
- Ulcers in the intestines, with symptoms such as abdominal pain and bleeding
- In men: low sperm count has been reported

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

- Increased sensitivity to sunlight and UV light

Additional side effects in children

Low blood sugar levels (Sweating more than usual, nausea, dizziness, confusion, etc.) have been reported in some children receiving Hanixol; however, most of the children were under the age of six years old and had a low body weight.

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 HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hanixol 50 mg Tablets

Keep this medicine out of the sight and reach of children.

Do not use Hanixol 50 mg Tablets after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

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 Hanixol 50 mg Tablets contain

The active ingredient is 6-mercaptopurine. One tablet contains 50 mg of Hanixol.

The other ingredients are: Lactose anhydrous; Maize starch; Starch, pregelatinized; Stearic acid; Magnesium stearate

What Hanixol 50 mg Tablets look like and contents of the pack

Hanixol 50 mg Tablets are round 7.4 mm yellowish tablets.

Type III 20 ml amber glass bottle containing 25 tablets with a polypropylene child-proof cap and silica gel desiccant.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Fontus Health Ltd

70 Northumberland Road,

Ballsbridge, Dublin 4,

D04 VH66

Ireland

Manufacturer:

Idifarma Desarrollo farmacéutico S.L.

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This leaflet was last approved in 11/2019

Other sources of information

To request the leaflet in Braille, large print or audio please contact the MA holder at the address above.