

Package leaflet: Information for the patient
Mercaptopurine Silver Pharma 50 mg tablets
mercaptopurine monohydrate

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

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2. What you need to know before you take Mercaptopurine Silver Pharma
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1. What Mercaptopurine Silver Pharma is and what it is used for

This medicine contains the active substance mercaptopurine monohydrate which belongs to a group of medicines called cytotoxics (also called chemotherapy). Mercaptopurine is used to treat leukaemia (cancer of the blood) and works by reducing the number of new blood cells your body makes.

Mercaptopurine is used to treat cancer of the blood (leukaemia) in adults, adolescents and children.

This is a fast-growing disease which increases the number of new white blood cells. These new white blood cells are immature (not fully formed) and unable to grow and work properly. They therefore cannot fight infections and may cause bleeding. Ask your doctor if you would like more explanation about this disease.

2. What you need to know before you take Mercaptopurine Silver Pharma

Do not take Mercaptopurine Silver Pharma:

- if you are allergic (hypersensitive) to mercaptopurine or any of the other ingredients of this medicine (listed in section 6).
- if you are just giving the vaccine of the yellow fever while taking mercaptopurine, because it may be fatal.

Warnings and precautions

Talk to your doctor or pharmacist before taking Mercaptopurine Silver Pharma if:

- you have been or you are going to be vaccinated against yellow fever. While you are taking mercaptopurine, administration of vaccines (such as the flu vaccine, mumps, BCG, etc.) is not recommended until your doctor tells you to do so. This is because some vaccines can cause an infection if they are given while you are taking this medicine.
- you have a liver or kidney problem; your doctor will monitor your liver or kidney function during the treatment and will reduce your dose, if required,
- you have a condition where your body produces too little of an enzyme called TPMT or 'thiopurine methyltransferase', your doctor may have to reduce the dose.

- you have a genetic disorder called Lesch-Nyhan syndrome, a rare disease that is included within inborn errors of metabolism,
- you are planning to have a baby. This applies to both men and women, mercaptopurine can be harmful to sperm or eggs (see 'Pregnancy, breast feeding and fertility' - below).

In some patients with inflammatory bowel disease who have received treatment with mercaptopurine, a rare and aggressive type of cancer called hepatosplenic T-cell lymphoma has developed (see section 4).

Taking mercaptopurine 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

If you are receiving immunosuppressive therapy, taking this medicine could put you at greater risk of:

- tumours, including skin cancer. Therefore, when taking this medicine, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- lymphoproliferative disorders
 - treatment with Mercaptopurine Silver Pharma 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).

Blood test

Treatment with mercaptopurine may affect your bone marrow. This means that there could be a decrease in the number of white blood cells, platelets, and (less frequently) red blood cells in your blood. Your doctor will perform blood tests every day during the initial period of your treatment (induction) and, at least, weekly during the most advanced period of your treatment (maintenance). This is in order to monitor the levels of these cells in your blood. If you stop taking treatment soon enough, your cell levels will return to normal.

Your doctor may order a blood test during your treatment with mercaptopurine to check your blood cell count. You may also ask for other genetic tests (for example, examining the TPMT and / or the NUDT15 genes) before or during the treatment to determine if the response to the medication may be affected due to your genes. Your doctor will adjust the dose of mercaptopurine depending on the results of these tests.

Other laboratory tests

Additional laboratory tests (urine, blood, etc.) may also be done according to your doctor's instructions.

Liver function

Mercaptopurine is toxic to the liver. For this reason, your doctor will perform weekly tests of your liver function while you are taking this medicine. If you have a pre-existing liver disease or you are taking other medications that could affect the liver, your doctor will perform tests more often. If you notice that the

white part of your eyes or your skin turns yellowish (jaundice) inform your doctor immediately since it may be necessary to stop the treatment immediately.

Infections

When you are treated with Mercaptopurine Silver Pharma the risk of viral, fungal and bacterial infections is increased and the infections may be more serious. See also section 4.

Tell your doctor before starting treatment whether or not you have had chickenpox, shingles or hepatitis B (a liver disease caused by a virus).

NUDT15-gene mutation

If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of Mercaptopurine Silver Pharma 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.

Sun and UV light

While taking mercaptopurine, you are more sensitive to sun and ultraviolet light. You should make sure to limit your exposure to sunlight and UV light, wear protective clothing and use a sunscreen with a high sun protection factor (SPF).

Vitamin B3 deficiency (pellagra)

Tell your doctor immediately if you have diarrhoea, localised pigmented rash (dermatitis) or deterioration of your memory, reasoning and thinking skills (dementia), as these symptoms may indicate a vitamin B3 deficiency. Your doctor will prescribe vitamin supplements (niacin/nicotinamide) to improve your condition.

Children and adolescents

There have been reports of hypoglycaemia (more sweating than usual, nausea, dizziness, confusion, etc.) in children who have been treated with mercaptopurine. Most of the reported cases were children under six years of age and low body weight.

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

Other medicines and Mercaptopurine Silver Pharma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. In particular, tell your doctor or pharmacist if you are taking any of the following:

- ribavirin (used to treat viral infections). It is not recommended concomitant use because cases of severe myelosuppression (reduction in formation of blood cell types) after administration jointly with mercaptopurine have been reported
- other cytotoxic medicines (chemotherapy) when used with mercaptopurine there is a greater chance of side effects, such as breathing problems
- other medicines whose primary or secondary toxicity is myelosuppression or reduction in formation of blood cell types (antineoplastic drugs such as "cyclophosphamide, dacarbazine, temozolomide, doxorubicin, cytarabine, capecitabine,etc").
- allopurinol, oxipurinol thiopurinol and febuxostat (used mainly to treat gout) – when used with mercaptopurine, only 25 % of the normal dose should be taken
- anticoagulants such as warfarin and Acenocoumarol (used to thin the blood and prevent blood clots)
- olsalazine or mesalazine (used for a bowel problem called ulcerative colitis)

- sulfasalazine (used for rheumatoid arthritis or ulcerative colitis)
- antiepileptics such as phenytoin or carbamazepine. It may be necessary to monitor blood concentrations of antiepileptic and adjust the dose if necessary
- 6-thioguanine (antineoplastic), since there is cross-resistance between both medicines
- methotrexate (used to treat cancer, rheumatoid arthritis or skin disease (severe psoriasis)), oral administration of methotrexate increases blood levels of mercaptopurine
- infliximab (used to treat certain bowel diseases (Crohn's disease and ulcerative colitis), rheumatoid arthritis, ankylosing spondylitis or skin disease (severe psoriasis))
- Azathioprine if an allergic reaction to mercaptopurine has occurred

Having vaccines while you are taking mercaptopurine

If you have recently been vaccinated or you are going to be vaccinated, it is important to check first with your doctor or nurse. While taking mercaptopurine, the administration of vaccines with living microorganisms (such as the flu vaccine, mumps, BCG, etc.) is not recommended until your doctor tells you to do so. This is because some vaccines can cause an infection if they are given while you are taking this medicine.

Mercaptopurine Silver Pharma with food and drink

This medicine can be taken with food or on an empty stomach. However, the method chosen must be the same every day.

Do not use mercaptopurine with milk or dairy products, as they may make the drug less effective. Mercaptopurine must be taken 1 hour before or 2 hours later after drinking milk or dairy products.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, this applies to both men and women, ask your doctor for advice before taking this medicine.

Pregnancy:

Mercaptopurine treatment during pregnancy is not recommended, mainly during the first trimester (three months), because it could cause damage to the fetus. If you are pregnant, your doctor will consider the risks and benefits for you and your baby before prescribing mercaptopurine

Do not take mercaptopurine if you are planning to have a baby. This applies to both men and women. This medicine may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are taking these tablets and for at least 3 months after stopping treatment. Ask your doctor for advice.

If you are pregnant, check with your doctor before taking mercaptopurine.

Taking Mercaptopurine Silver Pharma during pregnancy may cause severe, excessive itching without a rash. You may also experience nausea and loss of appetite at the same time, which may indicate a condition called cholestasis of pregnancy (a disease of the liver during pregnancy). Talk with your doctor immediately, as this condition can cause harm to your unborn child.

Breastfeeding:

Do not breast-feed while taking mercaptopurine. Ask your doctor or midwife for advice.

Driving and using machines

Mercaptopurine is not expected to affect your ability to drive or use machines, although there have been no studies to confirm this.

Mercaptopurine Silver Pharma contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Mercaptopurine Silver Pharma

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

Mercaptopurine should be administered only by a doctor with experience in treating blood diseases.

- Do not chew the tablet. Swallow your tablets whole with a glass of water.
- The tablets should not be split or crushed. If you need to split the tablet in two, or you, or your caregiver, handle broken tablets, do not inhale the dust of the tablet, and wash your hands immediately after handling.
- When you take mercaptopurine 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 your uric acid levels. Uric acid is a natural body chemical and its levels can rise while taking mercaptopurine.
- Your doctor may sometimes change your dose of mercaptopurine as a result of these tests.

The usual starting dose for adults and children is 50-75 mg/m² of your body surface area each day. Your doctor will calculate and adjust the dose taking into account your body weight, the results of blood tests, whether or not you are taking other medications for chemotherapy and your kidney and liver function. In some cases your doctor could change your dose of mercaptopurine. Consult your doctor or nurse if you have questions about the dose you should take.

It is important for you to take your treatment at night, it will be more effective. Mercaptopurine can be taken with food or on an empty stomach. However, the method chosen must be the same every day. It must be taken 1 hour before or 2 hours later after drinking milk or dairy products

If you take more Mercaptopurine Silver Pharma than you should

If you take more mercaptopurine than you should, tell your doctor immediately or go to a hospital straight away. You may have diarrhea or sickness. Take the medicine pack and this leaflet with you.

If you forget to take Mercaptopurine Silver Pharma

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

If you stop taking Mercaptopurine Silver Pharma

Do not stop taking your medicine except your doctor advice it or you may suffer a relapse of your illness. 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.

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

- An allergic reaction, the signs may include:
 - skin rashes
 - high temperature
 - joint pain
 - swollen face
 - skin nodules (erythema nodosum)
- 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), with abdominal pain and want to throw up, because it could be a sign of inflammation of the pancreas.
- any yellowing of the whites of the eyes or skin (jaundice),
- if you have diarrhoea,

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 white blood cells and platelets. (It can be detected in the blood).

Common (may affect up to 1 in 100 people)

- feeling or being sick (nausea or vomiting),
- liver problems – this may show up in your blood tests,
- decreased number of red blood cells that can cause fatigue, dizziness or shortness of breath - a condition called anemia
- loss of appetite
- diarrhea
- mouth inflammation (stomatitis)

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

- mouth ulcers
- inflammation of the pancreas which can give you abdominal pain or make you sick
- joint pain
- acne
- fever
- severe damage to liver cells (hepatic necrosis)

Rare: (may affect up to 1 in 1.000 people)

- hair loss
- in men: low sperm count
- swollen face
- various types of cancers including blood, lymph and skin cancers

Very rare: may affect up to 1 in 10.000 people

- another type of leukaemia

- ulcers in the intestines

Additional side effects: unknown frequent

- a rare type of cancer (hepatosplenic T-cell lymphoma), (see Section 2)
- skin nodules (erythema nodosum)
- burning or tingling sensation in the mouth or lips (inflammation of the mucosa, stomatitis)
- cracked or swollen lips (cheilitis)
- vitamin B3 deficiency (pellagra) associated with a localised pigmented skin rash, diarrhoea or decrease in memory, reasoning or other thinking skills.
- a decrease in clotting factors.

Additional side effects in children

- low blood sugar (hypoglycemia); unknown frequent

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

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 Mercaptopurine Silver Pharma

Keep this medicine out of the sight and reach of children, preferably in a locked locker. Accidental ingestion can be lethal for 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 Mercaptopurine Silver Pharma contains

- The active substance is mercaptopurine (as monohydrate). Each tablet contains 50 mg of mercaptopurine monohydrate..
- The other ingredients (excipient(s))are: Microcrystalline cellulose, povidone K30, croscarmellose sodium, lactosemonohydrate, magnesium stearate and stearic acid.

What Mercaptopurine Silver Pharma looks like and contents of the pack

Pale yellow 6 mm round tablets packed in two Alu-PVC blisters of 12 tablets each one, packed inside a carton pack.

Pack size: 24 tablets.

Marketing Authorisation Holder

Silver Pharma S.L
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This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal:	Mercaptopurina Silver 50 mg comprimidos
Austria:	Mercaptopurin Silver 50mg Tabletten
Denmark:	Mercaptopurin Silver Pharma
Norway:	Merkaptopurin Silver
Sweden:	Mercaptopurine Silver 50 mg tableter
Ireland:	Mercaptopurine Silver Pharma 50 mg tablets

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