

Thioprine

contains the active ingredient azathioprine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Thioprine.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Thioprine against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Thioprine is used for

Thioprine contains azathioprine as the active ingredient. Azathioprine belongs to a group of medicines called immunosuppressants.

These medicines work by blocking the activity of some parts of the body's immune system.

Thioprine is used to:

- prevent rejection after organ transplants
- treat autoimmune diseases, such as rheumatoid arthritis and SLE (systemic lupus erythematosus)
- treat certain skin, muscle and blood disorders.

Thioprine can also be used to treat other diseases called autoimmune diseases where your immune

system is reacting against your own body. These may include:

- severe rheumatoid arthritis
- systemic lupus erythematosus
- chronic active hepatitis
- certain skin, muscle, and blood diseases.

Ask your doctor if you have any questions about why Thioprine has been prescribed for you.

Your doctor may have prescribed Thioprine for another reason.

Thioprine is often taken together with other medicines, such as corticosteroids.

Thioprine is available only with a doctor's prescription.

There is no evidence that Thioprine is addictive.

Before you take Thioprine

When you must not take it

Do not take Thioprine if you are allergic to:

- medicines containing azathioprine (eg. Imuran, Azamun) or mercaptopurine (Puri-Nethol)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Thioprine if:

- you are pregnant, think you are pregnant or plan to become pregnant
- you plan to father a child.

This medicine may cause birth defects if either the male or female is taking it at the time of conception.

Do not take Thioprine if you are breastfeeding unless you and your doctor have discussed the risks and benefits involved.

It is not recommended for use while breastfeeding as it may cause serious side effects to your baby.

Do not take Thioprine if you have previously taken any of the following medicines for your rheumatoid arthritis:

- cyclophosphamide (eg. Cycloblastin)
- chlorambucil (Leukeran)
- melphalan (Alkeran).

It may not be safe for you to take Thioprine if you have taken any of the medicines in the past.

Ask your doctor if you are not sure if you have taken any of the medicines listed above in the past.

Do not take Thioprine if the expiry date (EXP.) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Thioprine if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Taking Thioprine while breastfeeding is not recommended. Your doctor will discuss the risks and benefits of taking Thioprine when breastfeeding.

Use effective contraception to prevent pregnancy while taking Thioprine. This applies to both partners.

Discuss this with your doctor.

Tell your doctor if you have any medical conditions, especially the following:

- liver disease
- kidney disease
- myasthenia gravis
- enlarged spleen
- Crohn's disease or ulcerative colitis
- thioprine methyltransferase (TPMT) enzyme deficiency
- Lesch-Nyhan syndrome.
- Hypersensitivity towards any medications (eg. 6-mercaptopurine)
- Hepatitis B

Tell your doctor if you have, have had or recently come in contact with anyone who has:

- chickenpox
- shingles
- an infection, especially with the varicella zoster virus.

Taking Thioprine can make these infections more severe or make some people more prone to developing these infections.

Tell your doctor and dentist if you need to have any dental work done.

If possible, dental work should be completed before starting Thioprine.

If you have not told your doctor about any of the above, tell them before you start taking Thioprine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Thioprine, or may affect how well it works. These include:

- other immune suppressants, such as tacrolimus (Prograf) or cyclosporin (eg. Neoral, Sandimmun), D-penicillamine (D-Penamine), infliximab
- allopurinol (eg. Zyloprim, Pro gout), oxipurinol or thiopurinol, a medicine used to treat gout
- xanthine oxidase inhibitors (eg. febuxostat)
- medicines used to treat cancer
- captopril (eg. Capoten, Acenorm), a medicine used to treat high blood pressure and certain heart conditions
- warfarin (Coumadin, Marevan), a medicine used to prevent blood clots
- vaccines or immunisations
- phenytoin (Dilantin) and phenobarbitone, medicines used to treat epilepsy or fits
- cimetidine (eg. Tagamet, Magicul), a medicine used to treat reflux and ulcers
- indomethacin (Indocid, Arthrexin), a medicine used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- rifampicin (Rifadin, Rimycin), ketoconazole and erythromycin (eg. EES, E-Mycin), antibiotics used to treat infections
- co-trimoxazole, used to treat infections
- tubocurarine, succinylcholine, used during anaesthesia
- mesalazine, olsalazine or sulphasalazine, used mainly to treat ulcerative colitis
- frusemide, may be used to reduce swelling caused by excess fluid
- methotrexate, used in the treatment of cancer

- ribavirin, used to treat a type of respiratory infection
- aminosaliclates, medicines used to treat bowel disorders such as Crohn's disease and ulcerative colitis, e.g., mesalazine (eg. Mesasal), olsalazine (Dipentum), sulfasalazine (eg. Salazopyrin).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Thioprine.

How to take Thioprine

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

Your doctor will tell you how many tablets you need to take each day and when to take them.

This depends on your condition, your body weight and whether or not you are taking any other medicines. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

From time to time, while you are taking Thioprine, your doctor will want you to have a blood test. This is to check your blood cell count and to change your dose if necessary.

How to take Thioprine

Swallow the tablets whole with a glass of water.

Do not break, crush or chew the tablets.

When to take Thioprine

Take Thioprine at least 1 hour before or 3 hours after food or milk.

This will reduce the chance of a stomach upset.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Thioprine for

Keep taking Thioprine for as long as your doctor recommends.

The length of time you are treated with Thioprine will depend on your condition. For those who have had transplants, use of Thioprine is usually long-term to reduce the risk of organ rejection.

For other conditions, your doctor will discuss with you how long you need to take this medicine. It could take some weeks or months for it to take full effect.

If you forget to take Thioprine

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much Thioprine (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), if you think you or anyone else may have taken too much Thioprine. Do this even if there

are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Thioprine

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Thioprine.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Thioprine.

If you become pregnant while taking Thioprine, tell your doctor immediately.

Visit your doctor regularly so that they can check on your progress.

You will need to have blood tests every week during the first eight weeks of treatment, and then once a month, while you are taking Thioprine.

If outdoors, wear protective clothing and use a 30+ sunscreen to protect yourself from the effects of the sun.

There have been reports of skin cancer occurring in transplant patients taking Thioprine.

Tell your doctor if you develop lumps anywhere in your body. Also, tell your doctor if you develop any new moles or notice changes in existing moles.

These changes may be early signs of cancer. Immune suppressant medicines, including Thioprine, may increase the risk of developing certain types of cancer, including skin cancer, lymphoma (cancer of the lymphatic system), sarcoma (cancer of the bone and soft tissues) and uterine cervical cancer. Talk to your doctor if you are concerned about this.

If you need to have surgery, tell your anaesthetist, surgeon or doctor or that you are taking Thioprine.

Since Thioprine is meant to be taken regularly every day, keep a continuous supply of medicine so you don't run out, especially over weekends or holidays.

Avoid contact with anyone suffering from chickenpox or shingles.

Infection with chickenpox or shingles can become severe in patients taking drugs such as Thioprine.

Things you must not do

Do not break, chew or crush the tablets.

Do not have any vaccinations or immunisations without first checking with your doctor.

Thioprine lowers your body's resistance to infection. You may develop the infection the vaccination/immunisation is meant to prevent.

Do not stop taking Thioprine, or lower the dose, without checking with your doctor.

Your doctor may want you to gradually reduce the amount of Thioprine you are taking before stopping completely.

Do not use Thioprine to treat any other conditions unless your doctor tells you to.

Do not give Thioprine to anyone else, even if they have the same condition as you.

Things to be careful of

If you are taking Thioprine after a transplant, avoid contact with people who have infections. Do not touch your eyes or the inside of your nose unless you have just washed your hands.

Due to the immune suppressant effects of Thioprine, you have an increased risk of getting infections after a transplant.

Be careful driving or operating machinery until you know how Thioprine affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Thioprine.

Like all other medicines, Thioprine may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following mild side effects and they worry you:

- any infection or fever
- unexpected bruising or bleeding more easily than normal, purplish-blue spots under the skin
- stiff neck and sensitivity to bright light
- bloody tarry stools or blood in the urine or stools
- nausea, vomiting, diarrhoea
- tiredness, dizziness or generally unwell
- irregular heart beat
- you come into contact with anyone who is suffering from chickenpox or shingles
- sores in the mouth and on the lips
- sensation of ants crawling over the skin
- changes in taste and smell.

Thioprine could cause your hepatitis B to become active again.

Tell your doctor immediately if you notice any of the following serious side effects:

- allergic type reactions e.g. skin rash, itching and difficulty breathing, wheezing or coughing.

- muscle weakness, with or without a skin rash
- muscle pain or stiffness
- severe joint pain
- kidney problems
- feeling faint especially when standing up
- severe abdominal pain
- diarrhoea
- jaundice, yellowing of the eyes or skin
- severe skin condition with blisters and bleeding in the lips, eyes, mouth, nose and genitals.

The above side effects require medical attention or even hospitalisation.

Side-effects reported particularly in organ transplant patients are:

- viral, fungal and bacterial infections
- hair loss (particularly following a kidney transplant)
- diarrhoea, usually with blood and mucus
- stomach pain with fever and vomiting.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you finish taking, Thioprine.

Other side effects not listed above may also occur in some people.

After taking Thioprine

Storage

Keep Thioprine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Thioprine or any other medicine in the bathroom or near a sink.

Do not leave Thioprine in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Thioprine, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Thioprine tablets are round, yellow, film-coated tablet, scored and marked "GX" above the score and "CH1" below the score on one side and blank on the reverse.

Each pack contains 100 tablets.

Ingredients

The active ingredient in Thioprine is azathioprine. Each Thioprine tablet contains 50 mg of azathioprine.

The tablets also contain the following inactive ingredients:

- lactose
- maize starch
- pregelatinised maize starch
- stearic acid
- magnesium stearate
- hypromellose
- macrogol 400.

The tablets are gluten free.

Supplier

Thioprine is supplied by:

Alphapharm Pty Limited
(ABN 002 359 739)
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.mylan.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

AUST R 57002.

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