

IMUPRINE

Azathioprine Tablets 50mg



What is in this leaflet

Please read this leaflet carefully before you start using IMUPRINE.

This leaflet answers some common questions about IMUPRINE. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of using IMUPRINE against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What IMUPRINE is used for

Your IMUPRINE tablets contain the active ingredient, azathioprine. It belongs to a group of medicines commonly known as immunosuppressants.

IMUPRINE is used to prevent the body rejecting organ transplants following surgery. It may also reduce the dose of corticosteroid treatment needed, and therefore, decrease the side effects associated with high dosage and prolonged usage of corticosteroids (e.g. prednisolone).

IMUPRINE is sometimes used to treat patients with moderate to severe Crohn's disease

IMUPRINE can be used alone or in combination with corticosteroids and with other medicines. It can help control diseases that involve the body's immune system such as:

- severe rheumatoid arthritis
- polyarteritis nodosa, a disease with inflammation of the arteries
- pemphigus vulgaris, an autoimmune disorder of the skin
- systemic lupus erythematosus (SLE)
- some forms of hepatitis
- certain types of blood diseases
- ulcerative colitis, an autoimmune disorder that affects the large colon

Your doctor may however, have prescribed IMUPRINE for another reason.

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

IMUPRINE is a very powerful medicine. **Do not** let anyone else take your medicine, even if his or her symptoms are similar to yours.

There is no evidence that IMUPRINE tablets are addictive.

IMUPRINE is available only with a prescription from your doctor.

Before you take IMUPRINE

When you must not use it

Do NOT take IMUPRINE if:

- **You are allergic to**

- **IMUPRINE, (azathioprine), 6-mercaptopurine (6-MP) or any of the other ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- **You are pregnant, intend to become pregnant or you intend to father a child**

Azathioprine is not recommended during pregnancy. It may cause birth defects if either the male or female are using it at the time of conception. Your partner should take adequate contraceptive precautions while you are taking IMUPRINE

- **You are breastfeeding.** IMUPRINE passes into the breast milk and may be harmful to your baby.

Do not use IMUPRINE after the expiry date (EXP) printed on the pack.

Do not use IMUPRINE if the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor if:

- **You are allergic to any medicines or foods**
- **You are pregnant, planning on becoming pregnant, or planning to father a child** IMUPRINE is not recommended during pregnancy.
- **You are breastfeeding or plan to breastfeed** IMUPRINE passes into breast milk and may seriously affect a

- breast-fed baby
- **You have recently been immunised or plan to do so**
- **You have, or have had kidney or liver disease (including hepatitis B)**
- **You have Lesch-Nyhan Syndrome (a metabolic disorder)**
- **You have a condition where your body does not produce enough of a natural chemical called thiopurine methyltransferase (TPMT)**
- **You have rheumatoid arthritis that has been previously treated by immunosuppressive therapy**
- **You have any other medical conditions**

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

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

You should also tell any health professional who is prescribing a new medication for you that you are taking IMUPRINE.

Some medicines may interfere with IMUPRINE. These include:

- Aminosalicylate derivatives, medicines used to treat inflammatory bowel disease e.g. olsalazine, mesalazine, sulphasalazine
- Allopurinol, oxypurinol, thiopurinol – medicines used to treat excess uric acid in the blood
- Furosemide – a diuretic
- Co-trimoxazole – an antibiotic
- Captopril – to treat high blood pressure
- Cimetidine which inhibits the production of acid in the stomach
- Indomethacin an anti-inflammatory medicine
- Some of the neuromuscular blocking agents including succinylcholine

- Medicines used to prevent blood clots such as warfarin
- Some other medications used to treat rheumatoid arthritis eg. penicillamine
- Some vaccines eg. the hepatitis B vaccination
- Methotrexate a medicine used in chemotherapy and to treat certain autoimmune disorders
- Ribavirin an antiviral medicine

These medicines may be affected by IMUPRINE or may affect how well IMUPRINE works. You may need different amounts of your medicines or you may need to take a different medicine. It is therefore important that you discuss this with your doctor or pharmacist.

Your doctor or pharmacist has more information on these medicines, and on other medicines that you need to be careful with, or to avoid while taking IMUPRINE.

How to use IMUPRINE properly

How much to take

Your doctor will tell you how much IMUPRINE you need to take each day. It is important that you take IMUPRINE only as directed by your doctor.

Your dose of IMUPRINE depends on your health condition, your response to the medicine and whether you are receiving other therapies at the same time. Your doctor may change the number of tablets you take, particularly at the beginning of treatment. **Do not take more than the recommended dose.**

Elderly patients can be more susceptible to the risk of side effects and so lower dosages are generally recommended.

In patients with kidney or liver problems, lower dosages are recommended.

If you do not understand the instructions printed on the label, ask your doctor or pharmacist for help.

How to take it

Swallow IMUPRINE tablets with a glass of water. Do not break, crush or chew the tablets.

It is advisable to take your IMUPRINE tablets at least 1 hour before or 3 hours after food or milk.

It is best to take your IMUPRINE tablets at the same time every day to help you remember to take them.

How long to take it

IMUPRINE helps to control your condition but does not cure it. It could take several weeks or months for IMUPRINE to take full effect.

For patients with a transplant, IMUPRINE must be taken everyday thereafter, to reduce the risks of the body rejecting a transplanted organ.

For other purposes, continue taking IMUPRINE for as long as your doctor prescribes.

If you forget to take it

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

This medicine is only to be taken by the person it was prescribed for. Do not give this medicine to anyone else.

While you are using IMUPRINE

Things you must do

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

Before you start any new medicine, tell your doctor or pharmacist that you are taking IMUPRINE.

Visit your doctor regularly, especially when you start using IMUPRINE.

Your doctor will be able to make sure that IMUPRINE is working properly and check for any unwanted side effects. You may be asked to have blood tests.

Tell your doctor if you plan to have any immunisations.

Tell your doctor if you come into contact with someone that is suffering from chickenpox or shingles.

If you are taking IMUPRINE long term your doctor may wish to check that your liver and kidney functions are not being affected.

The doctor will determine if this is necessary in a case-by-case manner.

Tell your doctor if you become pregnant while taking IMUPRINE.

Protect yourself from the sun while you are taking IMUPRINE.

If you go out in the sun, wear protective clothing and use sunscreen.

If you plan to have surgery, tell the surgeon or anaesthetist that you are taking IMUPRINE.

If you are going to have any blood tests, tell your doctor that you are taking IMUPRINE.

Things you must not do

Do not stop taking IMUPRINE or change the dose, without first checking with your doctor.

Do NOT give this medicine to anyone else, even if his or her symptoms seem similar to yours. This is very important as IMUPRINE is a very powerful medicine.

Things to be careful of

Be careful driving or operating machinery until you know how IMUPRINE tablets affect you.

IMUPRINE does not usually affect your ability to drive a car or operate machinery. However, as with many other medicines, IMUPRINE tablets may cause headache or dizziness in some people.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any IMUPRINE by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of IMUPRINE with you if you can.

Immediate toxic effects of an overdose include nausea, vomiting and diarrhoea. Long-term signs of overdosage may include unexplained infection, ulceration of the throat, bruising and bleeding and are a result of bone marrow depression (a reduction in the number of blood cells).

Keep telephone numbers for these places handy.

Side effects

Check with your doctor as soon as possible if you do not feel well while you are using

IMUPRINE. Do this even if you do not think the problems are connected with this medicine or are not listed in this leaflet.

Like all medicines, IMUPRINE can have some unwanted effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

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

- viral, fungal or bacterial infection
- hair loss
- fever and vomiting
- diarrhoea that may be associated with blood and mucous
- sores on the mouth and lips
- tiredness and generally feeling unwell

These are the more common side effects of IMUPRINE

Tell your doctor or pharmacist immediately if you notice any of the following:

- any infection or fever, unexpected bruising or bleeding, blood in the urine or stools
- severe stomach pain that may be associated with nausea, vomiting and fever
- dizziness, sleepiness, drowsiness and generally feeling unwell
- muscle pain, weakness or stiffness
- irregular heart beat
- coughing or difficulty breathing

The side effects listed above can be serious. You may need urgent medical attention.

If you notice yellow discolouration of the skin and eyes stop taking the IMUPRINE tablets immediately and contact your doctor.

IMMEDIATELY CONTACT YOUR DOCTOR or go to the accident and emergency department at your nearest

hospital if you observe any of the following symptoms:

- wheezing
- swelling of the face, lips, mouth or throat
- difficulty in breathing
- hives
- fainting.

These side effects can be very serious. If you experience any of them, you may be having an allergic reaction to IMUPRINE and you may need urgent medical attention.

All of these side effects are very rare.

If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

This list of possible side effects is not complete. Other effects may occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage conditions

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

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

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

Disposal

If your doctor tells you to stop taking IMUPRINE or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What IMUPRINE tablets look like

Each IMUPRINE tablet contains the active ingredient azathioprine.

IMUPRINE tablets 50mg are pale yellow film coated, round biconvex tablets marked with AE over 50 on one side and scored on the other side.

The tablets also contain maize starch, microcrystalline cellulose, lactose, purified water, magnesium stearate, purified talc and sodium starch glycollate.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
P O Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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