

NOUMED AZATHIOPRINE

azathioprine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED AZATHIOPRINE.

It does not contain all of the available information. 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 taking this medicine against the benefits it is expected to have for you or your child.

If your child is being treated with NOUMED AZATHIOPRINE, follow the same instructions in this leaflet as you would as the patient.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NOUMED AZATHIOPRINE is used for

NOUMED AZATHIOPRINE tablets contain the active ingredient azathioprine.

Azathioprine belongs to a group of medicines called immuno-suppressants. It works by reducing the body's own natural immunity.

This medicine is used to prevent the body from rejecting transplanted organs.

NOUMED AZATHIOPRINE can also be used to treat diseases involving the body's immune defence system such as:

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

This medicine is available only with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you take it

When you must not take it

Do not take this medicine if you have an allergy to:

- azathioprine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet.
- any other similar medicines such as mercaptopurine.

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

Do not take this medicine if you have been previously treated with alkylating agents (such as chlorambucil, melphalan or cyclophosphamide) for rheumatoid arthritis.

Do not take this medicine if you are pregnant, may be pregnant, intend to become pregnant or to father a child. It may cause birth defects if either the male or female is taking it at the time of

conception. It may also affect your developing baby if you take it during pregnancy. You and your partner should take adequate contraceptive precautions while you are taking NOUMED AZATHIOPRINE.

Do not breastfeed if you are taking this medicine unless you have discussed the risks and benefits with your doctor.

The active ingredient in NOUMED AZATHIOPRINE passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return the pack to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease
- liver disease
- spleen disorder
- a history of chickenpox or shingles
- hepatitis B
- a condition where your body produces too little of the natural chemical called thiopurine methyltransferase (TPMT)
- an inherited NUDT15 gene mutation where thiopurine-related side effects can increase
- Lesch-Nyhan syndrome
- any other medical conditions.

Tell your doctor if you have recently been vaccinated or immunised, or plan to do so. NOUMED AZATHIOPRINE may affect the way the vaccine works or your reaction to the vaccine.

Tell your doctor if you are currently having or planning to have dental treatment.

Any dental work should be done before treatment with NOUMED AZATHIOPRINE is started or delayed until your blood cell counts are normal.

Talk to your doctor if you are or may be pregnant, planning to become pregnant or father a child, are breastfeeding or planning to breastfeed.

If you have not told your doctor about any of the above, tell him/her before you start taking NOUMED AZATHIOPRINE.

Taking other medicines

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

Some medicines and NOUMED AZATHIOPRINE may interfere with each other. These include:

- allopurinol, febuxostat - medicines used to treat gout
- succinylcholine (suxamethonium), tubocurarine - medicines used to relax muscles during surgery
- other medicines used to suppress the body's immune defence system
- warfarin, acenocoumarol - medicines used to prevent blood clots
- aminosaliclates such as sulfasalazine, mesalazine or olsalazine - medicines used to treat inflammation of the bowel
- cimetidine - a medicine used to treat heartburn or stomach ulcers
- indometacin - a non-steroidal anti-inflammatory drug
- penicillamine - a medicine used to treat rheumatoid arthritis
- infliximab – used to treat various autoimmune diseases
- co-trimoxazole (trimethoprim + sulfamethoxazole), erythromycin - medicines used to treat bacterial infections
- rifampicin - a medicine used to treat tuberculosis
- ketoconazole - a medicine used to treat fungal infections
- furosemide (frusemide) - a diuretic medicine
- phenytoin, phenobarbital - medicines used to treat epilepsy
- methotrexate - used in the treatment of cancer
- ribavirin - used to treat a type of respiratory infection
- captopril, other ACE inhibitors - medicines used to treat high blood pressure.

These medicines may be affected by NOUMED AZATHIOPRINE or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will be able to tell you what to do when taking NOUMED AZATHIOPRINE with other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NOUMED AZATHIOPRINE.

How to take NOUMED AZATHIOPRINE

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

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you exactly how much NOUMED AZATHIOPRINE to take.

Your dose will depend on your body weight and how you respond to the medicine. Your doctor will determine the right dose for you. Your doctor may change the number of tablets you need to take, particularly at the beginning of treatment.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

Follow the instructions they give you.

If you take the wrong dose, NOUMED AZATHIOPRINE may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not break, chew or crush the tablets.

When to take it

Take it at least one hour before or three hours after food or milk.

If you take it on an empty stomach, it may increase the likelihood of vomiting, nausea (feeling sick) and stomach upsets.

Take your medicine at about the same time each day, preferably after a meal.

Taking it at the same time each day will help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Your doctor will discuss with you for how long you need to take your medicine. It could take some weeks or months for NOUMED AZATHIOPRINE to take full effect.

Transplant patients will need to take NOUMED AZATHIOPRINE continuously to reduce the risk of organ rejection.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

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

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much NOUMED AZATHIOPRINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep this telephone number handy.

While you are taking it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOUMED AZATHIOPRINE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, including any dental work, tell the surgeon, anaesthetist or dentist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, are trying to become pregnant or planning to father a child, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress and any unwanted side effects can be checked.

Your doctor may order regular blood tests to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you plan to have any immunisations or vaccinations.

If you come into contact with anyone who is suffering from chickenpox or shingles, tell your doctor immediately.

Always protect yourself from the sun while you are taking NOUMED AZATHIOPRINE.

Wear sunscreen, a hat and protective clothing.

Tell your doctor immediately if you notice any lumps on your body, any new moles or changes in existing moles or if you feel unwell.

NOUMED AZATHIOPRINE lowers your body's immune system and may increase your risk of skin and other cancers while you are taking this medicine.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take NOUMED AZATHIOPRINE to treat any other complaints unless your doctor tells you to.

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

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

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

Do not break, chew or crush the tablets.

Things to be careful of

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

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness may be worse.

Side effects

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

All medicines can have side effects. 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 the following lists of side effects. You may not experience any of them.

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

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

- any infection or fever
- unexpected bruising or bleeding, black tarry stools or blood in the urine or stools
- new marks on skin or any change to marks that may have been there previously
- tiny bumps on the skin that may enlarge and become tender
- headache, stiff neck and extreme sensitivity to bright light.
- nausea, vomiting
- tiredness, dizziness, or generally feeling unwell.
- irregular heart beat
- sores in the mouth and on the lips
- feeling of pins and needles, or 'ants' creeping in or under the skin
- changes in smell or taste
- yellowing of the skin and/or eyes (jaundice)

Azathioprine could cause your hepatitis B to become active again.

Side effects reported particularly in organ transplant patients are:

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- muscle weakness, tenderness, pain or stiffness
- severe joint pain
- kidney problems
- feeling faint, especially when standing up
- severe abdominal pain or stomach discomfort
- diarrhoea
- rash, itching, hives or other skin reactions such as blistering or peeling
- shortness of breath or wheezing

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

Some side effects, such as low blood cell count, can only be found when your doctor does tests from time to time to check your progress.

After taking it

Storage

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

If you take the tablets out of its original container, they may not keep well.

Keep your medicine in a cool, dry place, protected from light, where the temperature stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car especially on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine 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.

Disposal

If your doctor tells you to stop taking this medicine or its expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

NOUMED AZATHIOPRINE tablets are available in 2 strengths.

Both are round, biconvex, white to yellowish-white, film-coated tablets. The bigger 50 mg tablet has a one-sided breaking notch.

The tablets are packaged in blister packs of 100 tablets.

Ingredients

Active ingredient

NOUMED AZATHIOPRINE tablets contain 25 mg or 50 mg of azathioprine.

Inactive ingredients

- lactose monohydrate
- maize starch
- povidone
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- microcrystalline cellulose
- PEG-8 stearate
- purified talc
- titanium dioxide.

NOUMED AZATHIOPRINE tablets contain sugar (as lactose), but do not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Telephone 1800 930 999

Australian Registration numbers

25 mg: AUST R 298266

50 mg: AUST R 298267

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