



Patient Information Leaflet
Rotnos 50 mg Tablet
 azathioprine

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.

In this leaflet

- What Rotnos tablets are and what it is used for.
- What you need to know Before you take Rotnos tablets.
- How to take Rotnos tablets.
- Possible side effects.
- How to store Rotnos.
- Further information.

1. What Rotnos tablets are and what it is used for
 Rotnos tablets contain the active substance azathioprine. They belong to a group of medicines called immunosuppressives. This means that they reduce the strength of your immune system.
 Rotnos tablets may be used to help your body accept an organ transplant, such as a new kidney, heart or liver, or to treat some diseases where your immune system is reacting against your own body (autoimmune diseases).
 Autoimmune diseases may include:

- severe rheumatoid arthritis (a disease where the immune system attacks cells lining the joints causing swelling, pain, stiffness of the joints),
- systemic lupus erythematosus (a disease where the immune system attacks many of the body's organs and tissues, including skin, joints, kidneys, brain, and other organs causing severe fatigue, fever, stiffness and joint pain),
- dermatomyositis and polymyositis (a group of diseases causing inflammation of the muscles, muscle weakness and skin rash),
- auto-immune chronic active hepatitis (a disease in which the immune system attacks liver cells causing liver inflammation, fatigue, muscle aches, yellowing of the skin and fever),
- chronic refractory idiopathic thrombocytopenic purpura (a condition with low platelet counts, that can cause easy or excessive bruising and bleeding).

Rotnos tablets may also be used to treat inflammatory bowel disease (Crohn's disease or ulcerative colitis).
 Your doctor has chosen this medicine to suit you and your condition.
 Rotnos tablets may be used on its own, but it is more often used in combination with other medicines.

2. What you need to know before you take Rotnos tablets
Do not take Rotnos tablets:

- if you are allergic to azathioprine or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to mercaptopurine (a medicine which is similar to azathioprine the active substance contained in Rotnos tablets).

Warnings and precautions
 Talk to your doctor or pharmacist before taking Rotnos tablets:

- if you have recently received, or are due to receive, a vaccination (vaccine). If you take Rotnos tablets, 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 Rotnos tablets.
- if you have a genetic condition known as Lesch-Nyhan Syndrome. This is a rare condition that runs in families caused by a lack of something called HPRT or 'hypoxanthine-guanine-phosphoribosyltransferase'.
- if you have liver or kidney problems.
- if you have a genetic condition called TPMT deficiency (where your body produces too little of an enzyme called thiopurine methyltransferase).
- if you have ever had chickenpox or shingles.
- if you have had hepatitis B (a liver disease caused by a virus).
- if you are going to have an operation (this is because medicines including tubocurarine, or succinylcholine used as muscle relaxants during operations may interact with Rotnos tablets. You should inform your anaesthesiologist of your treatment with Rotnos tablets prior to surgery. If you are not sure if any of the above applies to you, talk to your doctor, nurse, or pharmacist before taking Rotnos tablets.

Your doctor will want to take **regular blood samples** while you are taking Rotnos tablets, to check for any changes (see section 3 "How to take Rotnos tablets. The frequency of your blood tests will usually decrease the longer you continue to take Rotnos tablets.
 If you are receiving immunosuppressive therapy, taking Rotnos could put you at greater risk of:

- tumors, including skin cancer. Therefore, when taking Rotnos, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- lymphoproliferative disorders
 - treatment with Rotnos 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).
- 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, severe chickenpox, or shingles infection.
- Therefore, when taking Rotnos tablets, avoid contact with people who have chickenpox or shingles.
- a previous hepatitis B infection becoming active again.
- other infections such as PML (Progressive Multifocal Leukoencephalopathy) which is an opportunistic infection. If you experience any signs of infection, please contact your doctor (see section 4 "Possible side effects").

Other medicines and Rotnos tablets.
 Tell your doctor if you are taking, have recently taken or might take any other medicines. This is because Rotnos tablets can affect the way some medicines work. Also, some other medicines can affect the way Rotnos works. In particular tell your doctor if you are taking, or are planning to take:

- ribavirin (used to treat viral infections)
- methotrexate (mainly used to treat cancers)
- allopurinol, oxipurinol, thiopurinol or other xanthine oxidase inhibitors, such as febuxostat (mainly used to treat gout)
- penicillamine (mainly used in the treatment of rheumatoid arthritis)
- ACE inhibitor (mainly used to treat high blood pressure – hypertension)
- anticoagulants such as warfarin or acenocoumarol (used to prevent blood clots)
- cimetidine (used to treat stomach ulcers and indigestion)
- indomethacin (used as a pain killer and anti-inflammatory)
- cytostatic drugs (drugs used to treat various types of cancer)
- aminosalicylates e.g. olsalazine, mesalazine or sulfasalazine (mainly used in the treatment of ulcerative colitis and Crohn's disease)
- co-trimoxazole (an antibiotic, used to treat infections caused by bacteria)
- infliximab (mainly used in the treatment of ulcerative colitis and Crohn's disease)
- Before a surgical procedure tell the anesthesiologist that you are taking azathioprine because muscle relaxants used during anesthesia may interact with azathioprine

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Rotnos tablets.

Having vaccines while you are taking Rotnos tablets
 If you are due to receive a vaccination (vaccine) speak to your doctor or nurse before you do so. If you take Rotnos tablets, you should not have a live 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 Rotnos tablets.

Rotnos tablets with food and drink
 You should take your medicine at least 1 hour before or 2 hours after having 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 become pregnant, ask your doctor for advice before taking this medicine.

Pregnancy
 Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner is taking Rotnos tablets.
 If you are pregnant your doctor will carefully consider whether you should take this medicine, based on the risks and benefits of treatment.

Breast-feeding
 Small amounts of Rotnos may pass into the breast milk. It is recommended that women receiving Rotnos should avoid breastfeeding unless the benefits outweighs the potential risks to the child. Ask your doctor for advice before breastfeeding.

Fertility
 The effects of Rotnos tablets on fertility are not known.

Driving and using machines
 Rotnos tablets are not known to affect your ability to drive or use machinery. If you experience any side effect from this medicine, you may not be able to drive or operate machinery.

Rotnos tablets contain lactose
 Rotnos tablets contain anhydrous lactose DT. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Rotnos tablets
 Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
 The quantity of Rotnos tablets taken may vary from patient to patient and will be prescribed by your doctor. The dose depends on the condition for which you are being treated.
 You can take Rotnos tablets with food or on an empty stomach, but the choice of method should be consistent from day to day. Some patients feel nausea (sick) when first given Rotnos tablets, this may be relieved by taking the tablets after food.

- When you take Rotnos 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 uric acid levels. Uric acid is a natural substance made in your body and levels of uric acid can rise while you are taking Rotnos tablets. High levels of uric acid may damage your kidneys

Your doctor may sometimes change your dose of Rotnos tablets as a result of these tests.
 Swallow your tablets whole. Do not chew the tablets. The tablets should not be broken or crushed.
 It is important that carers are aware of the need for safe handling of this medicine. If you or your caregiver does handle broken tablets, wash your hands immediately. Please consult your doctor or pharmacist for advice.

- Rotnos should be initiated and supervised by a physician experienced in immunosuppressive therapy.
- Rotnos is a hazardous drug. Need caution when handling Rotnos to minimize risk of exposure.
- Personal not taking Rotnos should not be exposed to it.

The recommended dose is:
Adults who have had an organ transplant: On the first day of treatment, the usual dose is up to 5 mg per kilogram of body weight, then a usual daily dose of 1 mg to 4 mg per kilogram of body weight. During treatment your doctor will adjust the dose depending on your reaction to the medicine.
Adults with other conditions: The usual starting dose is 1 mg to 3 mg per kilogram of body weight, then a usual daily dose of less than 1 mg to 3 mg per kilogram of body weight During treatment your doctor will adjust the dose depending on your reaction to the medicine.
 Elderly patients may need a reduced dose.
 Patients with kidney or liver problems may need a reduced dose.

Use in children
Children who have had organ transplant: The dosing for children who have had an organ transplant is the same as adults.
Children with other conditions: The dosing for children with other conditions is the same as adults.
 Children who are considered overweight may require a higher dose.

If you take more Rotnos tablets than you should
 If you take too many tablets, contact your doctor or pharmacist **immediately**.

If you forget to take Rotnos tablets
 Do not take a double dose to make up for the dose that you missed. Inform your doctor if you do miss a dose.
 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 it as soon as you remember, then go back to taking it as you would normally.

If you stop taking Rotnos tablets
 Before you stop taking Rotnos tablets, consult with your doctor or pharmacist. Do not stop taking Rotnos Tablets until your doctor tells you it is safe to do so.

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

4. Possible side effects
 Like all medicines, Rotnos Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:
Stop taking Rotnos tablets and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- allergic reactions, (these are uncommon side effects which may affect up to 1 in 100 people) the signs may include:
 - general tiredness, dizziness, feeling sick (nausea), being sick (vomiting), diarrhoea or abdominal pain
 - swelling of the eyelids, face, or lips
 - redness of the skin, skin nodules or a skin rash (including blisters, itching, or peeling skin)
 - pain in the muscles or joints
 - sudden wheeziness, coughing or difficulty breathing

In severe cases these reactions may be life-threatening (this is rare which may affect up to 1 in 10,000 people).

- Skin rashes or redness, which may develop into life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (toxic epidermal necrolysis) (these may be very rare side effects which may affect up to 1 in 10,000 people)
- Reversible pneumonitis (inflammation of your lungs causing breathlessness, cough, and fever) (these may be very rare side effects which may affect up to 1 in 10,000 people)
- problems with your blood and bone marrow, signs include weakness, tiredness, paleness, bruising easily, unusual bleeding or infections (these may be very common side effects which may affect more than 1 in 10 people)
- when Rotnos tablets is used in combination with other immunosuppressives you may get a virus which causes damage to your brain. This may cause headaches, changes in behaviour, impaired speech, worsening of abilities such as memory, attention and decision making (cognitive decline) and may be fatal (condition known as JC virus associated Progressive Multifocal Leukoencephalopathy) (these may be very rare side effects which may affect more than 1 in 10,000 people)

If you get any of the following serious side effects, talk to your doctor or specialist doctor immediately, you may need urgent medical treatment:

- you have a high temperature (fever) or other signs of an infection such as sore throat, sore mouth, urinary problems, or chest infection causing breathlessness and cough (these may be very common side effects which may affect more than 1 in 10 people).
- problems with your liver, signs include your skin, or the whites of your eyes turn yellow (jaundice) (these may be uncommon side effects which may affect up to 1 in 100 people).
- various types of cancers including blood, lymph, and skin cancers (see section 2 Warnings and precautions) (these may be rare side effects which may affect up to 1 in 1000 people).
- Sweet's syndrome (also known as acute febrile neutrophilic dermatosis). You may develop a rash (raised red, pink, or purple lumps which are sore to touch), particularly on your arms, hands, fingers, face and neck, which may also be accompanied by a fever (high temperature) (the rate at which these side effects occur is not known – cannot be estimated from available data).
- a certain type of lymphomas (hepatosplenic T-cell lymphoma). You may develop nose bleeds, fatigue, significant night sweats, weight loss and unexplained fevers (high temperature) (the rate at which these side effects occur is not known – cannot be estimated from available data).

If you notice any of the above, stop taking Rotnos tablets and see a doctor straight away.

Other side effects include:
Very Common (may affect more than 1 in 10 people)

- low white blood cell level in your blood tests, which may cause an infection

Common (may affect up to 1 in 10 people)

- nausea (feeling sick)

Uncommon (may affect up to 1 in 100 people)

- anaemia (low red blood cell level)
- pancreatitis (inflammation of the pancreas), which may cause severe upper stomach pain,

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

- You might notice some hair loss while taking Rotnos tablets. Often hair does grow again, even if you carry on taking Rotnos tablets. If you are worried ask your doctor.

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

- problems with your bowels leading to diarrhoea, abdominal pain, constipation, feeling or being sick (bowel perforation)

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

- photosensitivity (sensitivity to light or sunlight)
- You may develop a rash (raised red, pink, or purple lumps which are sore to touch), particularly on your arms, hands, fingers, face, and neck, which may also be accompanied by a fever (Sweet's syndrome, also known as acute febrile neutrophilic dermatosis). The rate at which these side effects occur is not known (cannot be estimated from available data).

5. How to store Rotnos
 Store below 30°C. Protect from light and moisture. Dispense in a tight, light-resistant container as defined in the USP. Keep out of the sight and reach of children.

6. Further information
What Rotnos contains
 The active substance is azathioprine.
 The other ingredients are Anhydrous Lactose DT, NF; Pregelatinized starch (STARCH 1500), NF; Povidone (Plasdone K-29/32), USP/NF; Alcohol SDA 23A; Purified water, USP; Magnesium Stearate (LIGAMED MF-2-V-MB), NF and Stearic acid, NF.

What Rotnos looks like and contents of the pack
 Rotnos tablets are yellow round tablet, scored on one side and product identification code "54 043" debossed on the other side.

Marketing Authorization Holder:
Anneal Pharmaceuticals of New York, LLC
 50 Horseblock Road, Brookhaven, NY 11719, USA

Manufactured by:
Anneal Pharmaceuticals Pvt. Ltd.
 Plot No. - 882/1-871, Near Hotel Kankavati,
 Sarkhej - Bavla Highway, Village: Rajoda, Tal. - Bavla,
 Dist. - Ahmedabad - 382220, Gujarat State, India

To report any side effect(s):

- Saudi Arabia:
 National Pharmacovigilance Center (NPC)
 - SFDA call center: 19999
 - E-mail: npc.drug@sfd.gov.sa
 - Website: <https://ade.sfd.gov.sa/>
- Other GCC States:
 Please contact the relevant competent authority.

This leaflet was last revised in 06/2025

To report any side effect(s):

- Saudi Arabia:
 • The National Pharmacovigilance Centre (NPC):
 - SFDA Call Center: 19999
 - E-mail: npc.drug@sfd.gov.sa
 - Website: <https://ade.sfd.gov.sa/>

This is a Medicament

– Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
 – Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 – The doctor and the pharmacist are experts in medicines, their benefits and risks.
 – Do not by yourself interrupt the period of treatment prescribed for you.
 – Do not repeat the same prescription without consulting your doctor.
 – Keep medicaments out of the reach of children.

Council of Arab Health Ministers
 Union of Arab Pharmacists

