

Package leaflet: Information for the patient

Imuran™ Film-coated Tablets 50mg

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.

What is in this leaflet

1. What Imuran Tablets are and what they are used for
2. What you need to know before you take Imuran Tablets
3. How to take Imuran Tablets
4. Possible side effects
5. How to store Imuran Tablets
6. Contents of the pack and other information

1. What Imuran Tablets are and what they are used for

Imuran Tablets belong to a group of medicines called immunosuppressives. This means that they reduce the strength of your immune system.

Immunosuppressive medicines are sometimes necessary to help your body accept an organ transplant, or to treat some diseases where your immune system is reacting against your own body (autoimmune diseases, such as rheumatoid arthritis).

2. What you need to know before you take Imuran Tablets

Do not take Imuran Tablets:

- if you are allergic (hypersensitive) to azathioprine or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to mercaptopurine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Imuran Tablets:

- if you suffer from the 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 suffer from liver or kidney problems
- if you are planning to become pregnant, or if your partner is planning to become pregnant (see section 2 "Pregnancy, breast-feeding and fertility")
- if you have a condition where your body produces too little of something called thiopurine methyltransferase (TPMT)
- if you have ever suffered from chickenpox or shingles
- if you are going to have a vaccination (see section 2 "Other medicines and Imuran Tablets").

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

Your doctor will want to take **regular blood samples** while you are taking Imuran Tablets, to check for any changes (see section 3 "How to take Imuran Tablets").

If you are receiving immunosuppressive therapy, taking Imuran Tablets could put you at greater risk of:

- tumours, including skin cancer. Therefore, when taking Imuran Tablets, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- severe chickenpox or shingles infection. Therefore, when taking Imuran Tablets, avoid contact with people who have chickenpox or shingles.
- 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 Imuran Tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Imuran can affect the way some medicines work. Also some other medicines can affect the way Imuran works. In particular tell your doctor if you are taking, or are planning to take:

- vaccines (used to prevent diseases) (see section 2 "Warnings and precautions")
- ribavirin (used to treat viral infections)
- methotrexate (mainly used to treat cancers)
- allopurinol, oxipurinol or thiopurinol (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 (includes some antibiotics and also 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).

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

Imuran Tablets with food and drink

Do not take Imuran Tablets less than 1 hour before, or less than 3 hours after eating any food, or drinking milk. You should swallow your tablet with some water (see section 3 "How to take Imuran Tablets").

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 (see section 2 "Warnings and precautions").

If you are pregnant or you are likely to become pregnant, you must consult your doctor before taking Imuran Tablets. Your doctor will carefully consider whether you should take this medicine, based on the risks and benefits of treatment.

You should not breast-feed during treatment with Imuran Tablets. This is because small amounts may pass into the breast milk.

Imuran Tablets may increase fertility in both male and female patients; therefore, while being treated with Imuran Tablets, you should take extra precautions, including using a contraceptive other than an intrauterine device (e.g. coil, Copper T).

Driving and using machines

Imuran 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.

Imuran Tablets contain lactose

Imuran Tablets contain lactose. 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 Imuran Tablets

Always take Imuran Tablets exactly as your doctor has told you. **Do not** change the dose or stop taking Imuran Tablets without first consulting your doctor. Check with your doctor or pharmacist if you are not sure.

The quantity of Imuran 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.

Your doctor will want to take **regular blood samples** while you are taking Imuran Tablets, to check for any changes (see section 2 "Warnings and precautions").

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 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 daily dose is 1 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

The dosing for children who have had an organ transplant is the same as adults.

Children who are considered overweight may require a higher dose.

Method of administration

Take Imuran Tablets as instructed by your doctor. It is important that you take this medicine on time. The pharmacy label tells you how much and how often you should take your medicine.

Swallow whole with a little water. The tablet should not be divided or broken.

Take Imuran tablets at least 1 hour before eating food or drinking milk, or at least 3 hours after eating food or drinking milk (see section 2 "Imuran Tablets with food and drink").

If you take more Imuran Tablets than you should

If you take too many tablets, contact your doctor or pharmacist **immediately**.

If you forget to take Imuran 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 Imuran Tablets

Before you stop taking Imuran Tablets, consult with your doctor or pharmacist. Do not stop taking Imuran 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, Imuran can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking Imuran and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- Allergic reaction, the signs may include
 - general tiredness, dizziness, feeling sick (nausea), being sick (vomiting) or diarrhoea
 - high temperature (fever), shivering or chills
 - redness of the skin or a skin rash
 - pain in the muscles or joints
 - changes in the amount and colour of the urine (kidney problems)
 - dizziness, confusion, feeling light headed or weak, caused by low blood pressure
- You bruise more easily or notice unusual bleeding
- You have a high temperature (fever) or other signs of an infection
- You feel extremely tired
- You notice lumps anywhere on your body
- You notice any changes to your skin, for example blisters or peeling
- Your health suddenly gets worse
- You come into contact with anyone who is suffering from chickenpox or shingles.

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

Other side effects include:

Very Common (affects more than 1 user in 10)

- infections caused by a virus, fungus or bacteria in transplant patients
- reduction in your bone marrow function, which may make you feel unwell or show up in your blood tests.

Common (affects 1 to 10 users in 100)

- nausea (feeling sick)
- low blood platelet level, which may cause you to bruise or bleed easily.

Uncommon (affects 1 to 10 users in 1,000)

- anaemia
- hypersensitivity reactions (allergic reactions)

- pancreatitis (inflammation of the pancreas), which may cause you severe upper stomach pain, with feeling sick (nausea) and being sick (vomiting)
- infections caused by a virus, fungus or bacteria
- liver problems, which may cause pale stools, dark urine, itchy skin and yellowing of your skin and eyes, and abnormalities in the results of liver function tests.

Rare (affects 1 to 10 users in 10,000)

- severe liver damage which can be life threatening
- hair loss
- problems with your blood and bone marrow (signs include weakness, tiredness, paleness, bruising or infections)
- various types of cancers including blood, lymph and skin cancers (see section 2 Warnings and precautions).

Very Rare (affects less than 1 user in 10,000)

- Inflammation of your lungs causing breathlessness, cough and fever
- Problems with your bowels leading to diarrhoea, abdominal pain, constipation, feeling or being sick (bowel perforation)
- 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*)

If you get any side effects, talk your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store Imuran Tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Imuran Tablets contain

- The active substance is azathioprine. Each Imuran Film-coated Tablet 50mg contains 50mg azathioprine.
- The other ingredients are:
Tablet core: lactose, pre-gelatinized starch, maize starch, stearic acid, magnesium stearate.

Tablet coating: hypromellose and macrogol 400.

What Imuran Tablets look like and contents of the pack

Imuran Film-coated Tablets 50mg are yellow, round, biconvex, film-coated tablet, scored and marked "GX CH1" on one side and plain on reverse.

Imuran Tablets are available in boxes of 100 tablets in blister packs (4 blister packs of 25 tablets).

Product procured from within the EU by the Parallel Product Authorisation Holder:

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157-173 Roden Street,
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Manufacturer:

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Repackaged by:

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Imuran™ Film-coated Tablets 50mg

azathioprine

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1. What Imuran Tablets are and what they are used for

Imuran Tablets belong to a group of medicines called immunosuppressives. This means that they reduce the strength of your immune system.

Immunosuppressive medicines are sometimes necessary to help your body accept an organ transplant, or to treat some diseases where your immune system is reacting against your own body (autoimmune diseases, such as rheumatoid arthritis).

2. What you need to know before you take Imuran Tablets

Do not take Imuran Tablets:

- if you are allergic (hypersensitive) to azathioprine or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to mercaptopurine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Imuran Tablets:

- if you suffer from the 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 suffer from liver or kidney problems
- if you are planning to become pregnant, or if your partner is planning to become pregnant (see section 2 "Pregnancy, breast-feeding and fertility")
- if you have a condition where your body produces too little of something called thiopurine methyltransferase (TPMT)
- if you have ever suffered from chickenpox or shingles
- if you are going to have a vaccination (see section 2 "Other medicines and Imuran Tablets").

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

Your doctor will want to take **regular blood samples** while you are taking Imuran Tablets, to check for any changes (see section 3 "How to take Imuran Tablets").

If you are receiving immunosuppressive therapy, taking Imuran Tablets could put you at greater risk of:

- tumours, including skin cancer. Therefore, when taking Imuran Tablets, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- severe chickenpox or shingles infection. Therefore, when taking Imuran Tablets, avoid contact with people who have chickenpox or shingles.
- 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 Imuran Tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Imuran can affect the way some medicines work. Also some other medicines can affect the way Imuran works. In particular tell your doctor if you are taking, or are planning to take:

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- indomethacin (used as a pain killer and anti-inflammatory)
- cytostatic drugs (includes some antibiotics and also 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).

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

Imuran Tablets with food and drink

Do not take Imuran Tablets less than 1 hour before, or less than 3 hours after eating any food, or drinking milk. You should swallow your tablet with some water (see section 3 "How to take Imuran Tablets").

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 (see section 2 "Warnings and precautions").

If you are pregnant or you are likely to become pregnant, you must consult your doctor before taking Imuran Tablets. Your doctor will carefully consider whether you should take this medicine, based on the risks and benefits of treatment.

You should not breast-feed during treatment with Imuran Tablets. This is because small amounts may pass into the breast milk.

Imuran Tablets may increase fertility in both male and female patients; therefore, while being treated with Imuran Tablets, you should take extra precautions, including using a contraceptive other than an intrauterine device (e.g. coil, Copper T).

Driving and using machines

Imuran 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.

Imuran Tablets contain lactose

Imuran Tablets contain lactose. 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 Imuran Tablets

Always take Imuran Tablets exactly as your doctor has told you. **Do not** change the dose or stop taking Imuran Tablets without first consulting your doctor. Check with your doctor or pharmacist if you are not sure.

The quantity of Imuran 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.

Your doctor will want to take **regular blood samples** while you are taking Imuran Tablets, to check for any changes (see section 2 "Warnings and precautions").

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 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 daily dose is 1 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

The dosing for children who have had an organ transplant is the same as adults.

Children who are considered overweight may require a higher dose.

Method of administration

Take Imuran Tablets as instructed by your doctor. It is important that you take this medicine on time. The pharmacy label tells you how much and how often you should take your medicine.

Swallow whole with a little water. The tablet should not be divided or broken.

Take Imuran tablets at least 1 hour before eating food or drinking milk, or at least 3 hours after eating food or drinking milk (see section 2 "Imuran Tablets with food and drink").

If you take more Imuran Tablets than you should

If you take too many tablets, contact your doctor or pharmacist **immediately**.

If you forget to take Imuran 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 Imuran Tablets

Before you stop taking Imuran Tablets, consult with your doctor or pharmacist. Do not stop taking Imuran 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, Imuran can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking Imuran and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- Allergic reaction, the signs may include
 - general tiredness, dizziness, feeling sick (nausea), being sick (vomiting) or diarrhoea
 - high temperature (fever), shivering or chills
 - redness of the skin or a skin rash
 - pain in the muscles or joints
 - changes in the amount and colour of the urine (kidney problems)
 - dizziness, confusion, feeling light headed or weak, caused by low blood pressure
- You bruise more easily or notice unusual bleeding
- You have a high temperature (fever) or other signs of an infection
- You feel extremely tired
- You notice lumps anywhere on your body
- You notice any changes to your skin, for example blisters or peeling
- Your health suddenly gets worse
- You come into contact with anyone who is suffering from chickenpox or shingles.

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

Other side effects include:

Very Common (affects more than 1 user in 10)

- infections caused by a virus, fungus or bacteria in transplant patients
- reduction in your bone marrow function, which may make you feel unwell or show up in your blood tests.

Common (affects 1 to 10 users in 100)

- nausea (feeling sick)
- low blood platelet level, which may cause you to bruise or bleed easily.

Uncommon (affects 1 to 10 users in 1,000)

- anaemia
- hypersensitivity reactions (allergic reactions)

- pancreatitis (inflammation of the pancreas), which may cause you severe upper stomach pain, with feeling sick (nausea) and being sick (vomiting)
- infections caused by a virus, fungus or bacteria
- liver problems, which may cause pale stools, dark urine, itchiness and yellowing of your skin and eyes, and abnormalities in the results of liver function tests.

Rare (affects 1 to 10 users in 10,000)

- severe liver damage which can be life threatening
- hair loss
- problems with your blood and bone marrow (signs include weakness, tiredness, paleness, bruising or infections)
- various types of cancers including blood, lymph and skin cancers (see section 2 Warnings and precautions).

Very Rare (affects less than 1 user in 10,000)

- Inflammation of your lungs causing breathlessness, cough and fever
- Problems with your bowels leading to diarrhoea, abdominal pain, constipation, feeling or being sick (bowel perforation)
- 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*)

If you get any side effects, talk your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store Imuran Tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Imuran Tablets contain

- The active substance is azathioprine. Each Imuran Film-coated Tablet 50mg contains 50mg azathioprine.
- The other ingredients are:
Tablet core: lactose, pre-gelatinized starch, maize starch, stearic acid, magnesium stearate.

Tablet coating: hypromellose and macrogol 400.

What Imuran Tablets look like and contents of the pack

Imuran Film-coated Tablets 50mg are yellow, round, biconvex, film-coated tablet, scored and marked "GX CH1" on one side and plain on reverse.

Imuran Tablets are available in boxes of 100 tablets in blister packs (4 blister packs of 25 tablets).

Product procured from within the EU by the Parallel Product

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157-173 Roden Street,
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