

Package leaflet: Information for the patient

Imatinib 400 mg Film-coated Tablets imatinib

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Imatinib is and what it is used for
2. What you need to know before you take Imatinib
3. How to take Imatinib
4. Possible side effects
5. How to store Imatinib
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1. What Imatinib is and what it is used for

Imatinib is a medicine containing an active substance called imatinib. This medicine works by inhibiting the growth of abnormal cells in the diseases listed below. These include some types of cancer.

Imatinib is a treatment for adults and children for

- **Chronic myeloid leukaemia (CML).** Leukaemia is a cancer of white blood cells. These white cells usually help the body to fight infection. Chronic myeloid leukaemia is a form of leukaemia in which certain abnormal white cells (named myeloid cells) start growing out of control.
- **Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph-positive ALL).** Leukaemia is a cancer of white blood cells. These white cells usually help the body to fight infection. Acute lymphoblastic leukaemia is a form of leukaemia in which certain abnormal white cells (named lymphoblasts) start growing out of control. Imatinib inhibits the growth of these cells.

Imatinib is also a treatment for adults for:

- **Myelodysplastic/myeloproliferative diseases (MDS/MPD).** These are a group of blood diseases in which some blood cells start growing out of control. Imatinib inhibits the growth of these cells in a certain subtype of these diseases.
- **Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL).** These are blood diseases in which some blood cells (named eosinophils) start growing out of control. Imatinib inhibits the growth of these cells in a certain subtype of these diseases.
- **Dermatofibrosarcoma protuberans (DFSP).** DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control. Imatinib inhibits the growth of these cells.

In the rest of this leaflet, we will use the abbreviations when talking about these diseases.

If you have any questions about how Imatinib works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Imatinib

Imatinib will only be prescribed to you by a doctor with experience in medicines to treat blood cancers or solid tumours.

Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Do not take Imatinib

- if you are allergic to imatinib or any of the other ingredients of this medicine listed in section 6. If this applies to you, **tell your doctor without taking Imatinib.**

If you think you may be allergic but are not sure, ask your doctor for advice.

Warnings and precautions

Talk to your doctor before taking Imatinib:

- if you have or have ever had a liver, kidney or heart problem.
- if you are taking the medicine levothyroxine because your thyroid has been removed.
- if you have ever had or might now have a hepatitis B infection. This is because Imatinib could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.
- if you experience bruising, bleeding, fever, fatigue and confusion when taking Imatinib, contact your doctor. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).

If any of these apply to you, **tell your doctor before taking Imatinib.**

You may become more sensitive to the sun while taking Imatinib. It is important to cover sun-exposed areas of skin and use sunscreen with high sun protection factor (SPF). These precautions are also applicable to children.

During treatment with Imatinib, tell your doctor straight away if you put on weight very quickly. Imatinib may cause your body to retain water (severe fluid retention).

While you are taking Imatinib, your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

Children and adolescents

Imatinib is also a treatment for children with CML. There is no experience in children with CML below 2 years of age. There is limited experience in children with Ph-positive ALL and very limited experience in children with MDS/MPD, DFSP and HES/CEL.

Some children and adolescents taking Imatinib may have slower than normal growth. The doctor will monitor the growth at regular visits.

Other medicines and Imatinib

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (such as paracetamol) and including herbal medicines

(such as St. John's Wort). Some medicines can interfere with the effect of Imatinib when taken together. They may increase or decrease the effect of Imatinib, either leading to increased side effects or making Imatinib less effective. Imatinib may do the same to some other medicines.

Tell your doctor if you are using medicines that prevent the formation of blood clots.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- Imatinib is not recommended during pregnancy unless clearly necessary as it may harm your baby. Your doctor will discuss with you the possible risks of taking Imatinib during pregnancy.
- Women who might become pregnant are advised to use effective contraception during treatment.
- Do not breast-feed during the treatment with Imatinib.
- Patients who are concerned about their fertility while taking Imatinib are advised to consult with their doctor.

Driving and using machines

You may feel dizzy or drowsy or get blurred vision while taking this medicine. If this happens, do not drive or use any tools or machines until you are feeling well again.

3. How to take Imatinib

Your doctor has prescribed Imatinib because you suffer from a serious condition. Imatinib can help you to fight this condition.

Always take this medicine exactly as your doctor or pharmacist has told you. It is important that you do this as long as your doctor or pharmacist tells you to. Check with your doctor or pharmacist if you are not sure.

Do not stop taking Imatinib unless your doctor tells you to. If you are not able to take the medicine as your doctor prescribed or you feel you do not need it anymore, contact your doctor straight away.

How much Imatinib to take

Use in adults

Your doctor will tell you exactly how many tablets of Imatinib to take.

- **If you are being treated for CML:**

Depending on your condition the usual starting dose is either 400 mg or 600 mg:

- 400 mg to be taken as 1 tablet **once** a day
- 600 mg to be taken as 1 tablet of 400 mg plus 2 tablets of 100 mg **once** a day.

For CML your doctor may prescribe a higher or lower dose depending on how you respond to the treatment. If your daily dose is 800 mg (2 tablets), you should take one tablet in the morning and a second tablet in the evening.

- **If you are being treated for Ph-positive ALL:**

The starting dose is 600 mg to be taken as one tablet of 400 mg plus 2 tablets of 100 mg **once** a day.

- **If you are being treated for MDS/MPD:**

The starting dose is 400 mg to be taken as one tablet **once** a day.

- **If you are being treated for HES/CEL:**

The starting dose is 100 mg, to be taken as one tablet of 100 mg **once** a day. Your doctor may decide to increase the dose to 400 mg, to be taken as one tablet of 400 mg **once** a day, depending on how you respond to treatment.

- **If you are being treated for DFSP:**

The dose is 800 mg per day (2 tablets), to be taken as one tablet in the morning and a second tablet in the evening.

Use in children and adolescents

The doctor will tell you how many tablets of Imatinib to give to your child. The amount of Imatinib given will depend on your child's condition, body weight and height. The total daily dose in children must not exceed 800 mg with CML and 600 mg with Ph+ ALL. The treatment can either be given to your child as a once-daily dose or alternatively the daily dose can be split into two administrations (half in the morning and half in the evening).

When and how to take Imatinib

- **Take Imatinib with a meal.** This will help protect you from stomach problems when taking Imatinib.
- **Swallow the tablets whole with a large glass of water.**

If you are unable to swallow the tablets, you can dissolve them in a glass of still water or apple juice:

- Use about 200 ml for each 400 mg tablet.
- Stir with a spoon until the tablets have completely dissolved.
- Once the tablet has dissolved, drink everything in the glass straight away. Traces of the dissolved tablets may be left behind in the glass.

How long to take Imatinib

Keep taking Imatinib every day for as long as your doctor tells you.

If you take more Imatinib than you should

If you have accidentally taken too many tablets, talk to your doctor **straight away**. You may require medical attention. Take the medicine pack with you. Symptoms of an overdose include feeling sick, being sick, diarrhoea, rash, red skin, tiredness, uncontrollable movements, muscle pain, stomach pain, headache, decreased appetite, weakness and high temperature.

If you forget to take Imatinib

- If you forget a dose, take it as soon as you remember. However if it is nearly time for the next dose, skip the missed dose.
- Then continue with your normal schedule.
- Do not take a double dose to make up a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. They are usually mild to moderate.

Some side effects may be serious. Tell your doctor straight away if you get any of the following:

Very common (may affect more than 1 in 10 people):

- Changes in the number of blood cells, which may cause signs of infection such as fever, severe chills, sore throat or mouth ulcers (changes in the number of white blood cells), pale skin, feeling tired and breathless and having dark urine (low numbers of red blood cells), bleeding or bruising for longer than normal or unexpectedly, when you have not hurt yourself (changes in the number of platelets).
- Rapid weight gain. Imatinib may cause your body to retain water (severe fluid retention).

Uncommon (may affect up to 1 in 100 people):

- Fever with shivering, fast heartbeat, fast breathing and/or confusion (signs of sepsis, a serious reaction to an infection)
- Chest pain (possibly spreading to the arms), irregular heart rhythm, shortness of breath, swelling of the feet or legs due to fluid build-up (signs of heart problems).
- Cough, having difficulty breathing or painful breathing (signs of lung problems).
- Feeling sick (nausea), with loss of appetite, dark-coloured urine, yellow skin or eyes (signs of liver problems).
- Rash, red skin with blisters on the lips, eyes, skin or mouth, peeling skin, fever, raised red or purple skin patches, itching, burning sensation, pustular eruption (signs of skin problems).
- Severe pain in the abdomen, blood in your vomit or stools, black stools (signs of gastrointestinal disorders).
- Severely decreased urine output, feeling thirsty, dehydration, nausea, loss of appetite, weakness, fatigue, headaches, feeling generally ill (signs of kidney disease).
- Severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system problems such as bleeding or swelling in skull/brain).
- Eye pain or deterioration in vision. Bleeding in the eyes.
- Sudden swelling and redness of the skin (signs of a skin infection called cellulitis).
- Difficulty hearing.
- Muscle weakness and spasms with an abnormal heart rhythm (signs of changes in the amount of potassium in your blood).
- Severe upper stomach pain, often with feeling sick (nausea) and being sick (vomiting).
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory test results (e.g. high potassium, uric acid and calcium levels and low phosphorous levels in the blood).

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

- Muscle spasms with a fever, red-brown urine, pain or weakness in your muscles (signs of muscle problems).
- Feeling sick (nausea) with diarrhoea and being sick (vomiting), persistent constipation, abdominal pain or fever (signs of bowel problems).
- Pelvic pain sometimes with nausea and vomiting, with unexpected vaginal bleeding, feeling dizzy or fainting due to low blood pressure (signs of problems with your ovaries or womb).
- Blood clots in small blood vessels (thrombotic microangiopathy).

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

- Pain in your hips or difficulty walking.
- Slowing of growth in children and adolescents.
- Chronic kidney failure.
- Severe allergic reaction with rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- Sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness, heat or swelling in the arms and legs (signs of a blockage of a blood vessel caused by a blood clot).

- Allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells (DRESS syndrome). Symptoms include skin rash, fever, swollen glands that do not go away, yellowing of your skin or of the whites of the eyes, unusual bruising or bleeding, unexpected muscle pain, frequent infections.
- Recurrence (reactivation) of Hepatitis B infection when you have had hepatitis B in the past (a liver infection).

If you get any of the above, **tell your doctor straight away.**

Other side effects may include:

Very common (may affect more than 1 in 10 people):

- Headache or feeling tired.
- Feeling sick (nausea), being sick (vomiting), diarrhoea or indigestion.
- Rash.
- Muscle spasms, cramps, or joint, muscle or bone pain during treatment or after you have stopped taking Imatinib
- Swelling such as round your ankles or puffy eyes.
- Weight gain.

If any of these affects you severely, **tell your doctor.**

Common (may affect up to 1 in 10 people):

- Anorexia, weight loss or a disturbed sense of taste.
- Feeling dizzy or weak.
- Difficulty in sleeping (insomnia).
- Discharge from the eye with itching, redness and swelling (conjunctivitis), watery eyes or having blurred vision.
- Nose bleeds.
- Pain or swelling in your abdomen, flatulence, heartburn or constipation.
- Itching.
- Unusual hair loss or thinning.
- Numbness or tingling of the hands or feet.
- Joint pain with swelling.
- Dry mouth, dry skin or dry eye.
- Decreased or increased skin sensitivity.
- Increased skin sensitivity to light.
- Hot flushes, chills or night sweats.
- Increased levels of liver enzymes, which would be seen in a blood test.

If any of these affects you severely, tell your doctor.

Uncommon (may affect up to 1 in 100 people):

- Depression, anxiety.
- Problems with memory.
- Generally feeling unwell.
- High blood pressure.
- Feeling light-headed, dizzy or fainting (signs of low blood pressure).
- Feeling drowsy or sleepy.
- Restless leg, shaking (tremor).
- Pain in the lower back, spreading to the legs (sciatica).
- Spinning sensation (vertigo).

- Ringing in the ear.
- Increased sweating.
- Increased appetite.
- Breaking of the fingernails or toenails.
- Changes in the colour of the skin.
- Skin rash, often painful, with blisters (shingles).
- Numb or cold toes and fingers (signs of Raynaud's syndrome).
- Pain, discomfort or difficulty when swallowing.
- Sore mouth, dry or cracked lips, mouth ulcers.
- Cold sores.
- Belching.
- Stiffness of the joints or muscles.
- Urinating more frequently, pain when urinating, cloudy urine or blood in the urine.
- Heavy menstrual periods or irregular periods.
- Breast enlargement (also in men), nipple pain.
- Swollen glands in the neck, armpit or groin
- Swelling of the scrotum.
- Sexual problems, including difficulty in obtaining or maintaining an erection in men and reduced sex drive.
- Changes to the levels of some chemicals in the blood, which may be used to measure how your body is working and would be seen in a blood test.

If any of these affects you severely, tell your doctor.

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

- Confusion.
- Fits (convulsions).
- Changes in nail colour.

If any of these affects you severely, tell your doctor.

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

- Reddening and/or swelling on the palms of the hands and soles of the feet which may be accompanied by tingling sensation and burning pain.
- Painful and/or blistering skin lesions.

If any of these affects you severely, **tell your doctor.**

Reporting of side effects

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

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; website: <http://www.hpra.ie>; e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Imatinib

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

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

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Imatinib contains

- The active substance is imatinib mesilate. Each tablet of Imatinib contains imatinib mesilate equivalent to 400 mg imatinib.
- The other ingredients are, microcrystalline cellulose (E460), low substituted hydroxypropyl cellulose (E463), povidone (E1201), crospovidone (Type A) (E1202), silica colloidal anhydrous, magnesium stearate (E572).
- The tablet coating is made of hypromellose (E464), Macrogol 400, talc (E553b), red iron oxide (E172), yellow iron oxide (E172).

What Imatinib looks like and contents of the pack

Imatinib 400 mg Film-coated Tablets are dark yellow to brownish-orange, ovaloid shaped, film-coated tablets with a breakline on one side and '400' on the other side. The tablet can be divided into equal doses.

They are supplied in blister packs containing 10, 30, 30 x 1 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd., T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer

Remedica Ltd, Acharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Imatinib Mylan 400 mg filmtabletten
Belgium	Imatinib Mylan 400 mg filmomhulde tabletten
Cyprus	Imatinib Mylan 400 mg Film-coated Tablets
Czech Republic	Imatinib Mylan 400 mg potahované tablety
Denmark	Imatinib Mylan
Finland	Imatinib Mylan 400 mg kalvopäällysteiset tabletit
France	Imatinib Mylan 400 mg comprimé sécable
Germany	Imatinib Mylan 400 mg Filmtabletten
Greece	Imatinib Mylan 400 mg Film-coated Tablets
Hungary	Imatinib Mylan 400 mg filmtabletta
Iceland	Imatinib Mylan 400 mg filmuhúðaðar töflur
Ireland	Imatinib 400 mg Film-coated Tablets
Italy	Imatinib Mylan
Luxembourg	Imatinib Mylan comprimés pelliculés
Malta	Imatinib Mylan
Norway	Imatinib Mylan 400 mg filmdrasjerte tabletter
Portugal	Imatinib Mylan
Slovakia	Imatinib Mylan 400 mg
Slovenia	Imatinib Mylan 400 mg filmsko obložene tablete

Spain	Imatinib Mylan 400 mg comprimidos recubiertos con película EFG
Sweden	Imatinib Mylan 400 mg filmdragerade tabletter
The Netherlands	Imatinib Mylan 400 mg, filmomhulde tabletten
United Kingdom	Imatinib 400 mg Film-coated Tablets

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