

# New Zealand Consumer Medicine Information

## Imatinib

100 mg (60 capsules) and 400 mg (30 capsules)

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### What is in this leaflet

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The information enclosed answers several general questions about Imatinib.

This leaflet does not include all the accessible information on Imatinib.

All medication has benefits and risks. Your doctor will have considered the risks of you using Imatinib against the benefits expected.

Discuss with your doctor any concerns you may have.

This leaflet was last updated on the date at the end of the leaflet.

Check with your doctor or pharmacist to make sure you have the most up to date information on Imatinib as there may be new information available.

The most recent leaflet available for Imatinib can be found at [www.medsafe.govt.nz](http://www.medsafe.govt.nz)

**Keep this information with your medicine and refer to this leaflet if you have any queries.**

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### What Imatinib is used for

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Imatinib is used for the treatment of chronic myeloid leukaemia (CML) in adults and children and acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL) in adults.

In these categories of leukaemia (CML and ALL), white blood cells grow uncontrolled due to an enzyme that is produced by an abnormal chromosome.

Imatinib works by destroying the abnormal cells while not affecting the normal cells. Imatinib works by reducing the growth of the abnormal cells.

Other treatments that Imatinib is used for in adults are:

- ***Hypereosinophilic syndrome (HES) and/or Chronic eosinophilic leukaemia (CEL).***

Blood diseases where “eosinophils” (a type of blood cell) start to grow uncontrolled.

- ***Systemic mastocytosis (SM).***

A cancer where particular blood cells, named “mast” cells, grow uncontrollably.

- ***Gastro-intestinal stromal tumours (GIST).***

A cancer of the stomach and bowels that affects the tissue surrounding the stomach and bowels and the cells grow uncontrollably.

- ***Dermatofibrosarcoma protuberans (DFSP).***

A tissue cancer where certain cells underneath the skin starts to grow uncontrolled.

- ***Myelodysplastic/myeloproliferative diseases (MDS/MPD).***

Blood diseases where certain blood cells start to grow uncontrolled.

If you have any concerns about why Imatinib has been prescribed, please discuss this with your doctor.

Your doctor may have prescribed Imatinib for a different reason.

Imatinib is only accessible with a prescription from your doctor.

Imatinib is not addictive.

### ***Children and adolescents***

Imatinib is not proposed for the treatment of children under three years of age as the effectiveness and safety of the medication is yet to be established.

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## **Before you use Imatinib**

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

### ***Do not use Imatinib if you:***

- Are allergic to imatinib, or any of the other ingredients in Imatinib (listed on the back of this leaflet).

Seek immediate medical attention if you experience any of the following side effects, as you may be allergic to this medicine:

- Itching, rash or hives on the skin.
- Swelling of the lips, tongue, face or other body parts
- Increase in wheezing, shortness of breath, or breathing difficulty.

Please inform your doctor **before** using Imatinib if you are currently being treated or have in the past been treated for any other medical conditions, in particular the following:

- Heart problems.
- Kidney problems.
- Liver problems and/or hepatitis B infection. During treatment with Imatinib, hepatitis B (an infection of the liver) may become active again.
- Your thyroid gland has been removed.

It is important you discuss the above conditions with your doctor as some of these problems may become worse during Imatinib treatment. Your doctor may change your treatment due to the above conditions, if required.

### ***Pregnancy and breastfeeding***

Imatinib is not recommended for use when you are pregnant or your partner is pregnant. This is consistent with most other medications used for the treatment of cancer.

If you are pregnant, think you might be pregnant, planning to get pregnant or breastfeeding, you must talk to your doctor before starting to take Imatinib.

While taking Imatinib, it is essential that both women and men use effective contraception throughout treatment and for a period of fifteen days after treatment.

If pregnancy occurs despite using contraceptive methods, discuss with your doctor immediately.

Discuss with your doctor if you are wanting to make your partner pregnant.

Imatinib should not be used if you are breastfeeding. If you are prescribed Imatinib while you are breastfeeding, breastfeeding should be stopped and different feeding arrangements, for example, bottle feeding should be made available for your baby. Your doctor will advise you when it is safe to resume breastfeeding.

**Do not use after the expiry date. The expiry date can be found on the blister and on the carton.**

**If the packaging of the Imatinib carton or blister displays signs of damage or tampering do not use.**

### ***Using other medicines***

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription from your pharmacy, health store or supermarket.

If you use Imatinib with some other medications, the effect of Imatinib on the other medicine may be altered. This includes medications that are primarily removed from the body via the liver.

Tell your doctor if you are taking:

- Antibiotics that are used for bacterial and/or fungal infections (such as clarithromycin, erythromycin, itraconazole and rifampicin).
- Cyclosporin.
- Dexamethasone (a steroid medication).
- Medication to treat epilepsy (such as carbamazepine, phenobarbital or phenytoin).
- Medication to treat high cholesterol levels in the blood (such as simvastatin).
- Medication to treat HIV infections and AIDS.
- Paracetamol which is found in many well-known cold and flu medicines and pain relievers.
- Medication to treat depression and mental disorders.
- Medication to treat heart concerns and high blood pressure.
- St. John's Wort (*Hypericum perforatum*) which is used for several conditions and can be found in many non-prescription products.
- Warfarin (a medication to treat and prevent blood clots).

Your doctor will discuss with you what to do if you are taking any of the above medications. Your doctor may instruct you to take a modified amount of the above medications or you may be instructed to change your medication completely.

### ***Driving and using machines***

Make sure you are aware of how Imatinib affects you before driving or operating tools and machinery. In some people, Imatinib can cause light-headedness or dizziness.

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## **Using Imatinib**

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It is important that you follow the prescribed instructions your doctor gave you on the dosage of Imatinib and the duration you should take it.

### ***Adult dosage***

#### ***Chronic myeloid leukaemia (CML):***

The standard dose is 400 to 600 mg per day. 800 mg is the maximum dose per day.

The dose is determined by the CML stage you have.

For children, the Imatinib dose is determined based on the child's size.

***Philadelphia chromosome positive (Ph-positive ALL):***

The standard dose is 600 mg per day.

***Systemic mastocytosis (SM), Hypereosinophilic syndrome and or chronic eosinophilic leukaemia (HES/CEL):***

The standard starting dose is 400 mg per day. Some individuals may have a starting dose that is less at 100 mg.

***Gastro-intestinal stromal tumours (GIST):***

The standard dosage is 400 mg or 600 mg per day.

***Dermatofibrosarcoma protuberans (DFSP):***

The standard starting dose is 800 mg a day.

***Myelodysplastic / myeloproliferative diseases (MDS/MPD):***

The standard starting dose is 400 mg per day.

***Dosage instructions***

If your daily dosage is 400 mg, one capsule of 400 mg should be taken once per day.

If your daily dosage is 600 mg:

- six capsules of 100 mg each, or
- one capsule of 400 mg and two capsules of 100 mg taken once per day.

If your daily dosage is 800 mg, one capsule of 400 mg should be taken twice per day, once in the morning and once in the evening.

When taking Imatinib, dependent on your response to the medication, your doctor may instruct you to have more or less than the recommended daily dosage or discontinue your treatment altogether.

Most of the time, Imatinib is taken as a single dose once per day. In some cases, your doctor may instruct you to take part of your dosage of Imatinib in the morning and part in the evening.

***Children***

For children and adolescents, the total dose of Imatinib taken daily should not exceed 600 mg. This is either taken once per day or in two divided doses (morning and at night).

Imatinib may cause some children and adolescents to have slower than normal growth. This will be monitored carefully by your doctor at your regular appointments.

### ***How to take Imatinib***

Take each dose of Imatinib immediately after a meal or with food with a large glass of water. This will help prevent irritation to your stomach and oesophagus.

### ***How long should you use Imatinib***

While taking Imatinib, your doctor will monitor your progress closely to make sure the medicine is working as it should. Make sure you continue to take your Imatinib for as long as your doctor thinks is necessary.

### ***If you have difficulty swallowing***

If you are not able to swallow your medication, you can open the capsule and pour the powder capsule contents into a glass of still water or apple juice at room temperature (50 mL for 100 mg capsule or 200 mL for a 400 mg capsule) and stir with a spoon.

The capsule contents mixture should be taken immediately after mixing is complete in the water or apple juice.

**You should handle the capsule contents with caution in order to avoid skin-eye contact or inhalation.**

**Women who are pregnant or likely to become pregnant should also handle the contents with caution in order to avoid skin-eye contact or inhalation.**

**You should wash your hands immediately after opening the capsules.**

Taking Imatinib at approximately the same time each day will help you to remember when to take your capsules and will give you the best effect of the medication.

Discuss with your doctor if you have any questions about the dose you have been prescribed.

### ***If you forget to take your Imatinib***

If you have forgotten to take your normal dose at the correct time, take your next dose as soon as you remember. However, if you forget to take your Imatinib close to the time of the next dose then simply miss out the dose you have forgotten.

**Do not take a double dose of Imatinib at any given time if you have missed a dose.**

If you have difficulty remembering when the next dose of your Imatinib is due, talk to your pharmacist for advice.

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## **In case of overdose**

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### ***If you have taken more Imatinib than you should (overdose)***

**If you or someone else takes too much of your Imatinib, immediately phone the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or your doctor or go to your nearest Accident and Emergency department even if you do not feel unwell or there are no signs of overdose symptoms. It is possible you require urgent medical attention.**

**Keep these telephone numbers and information in an easily accessible place.**

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## **While you are using Imatinib**

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**Abide by all instructions given by your doctor carefully as they may be different from the information provided in this leaflet.**

**Make sure you attend all doctor's appointments in relation to your treatment with Imatinib so that your progress can be reviewed.**

While taking Imatinib you will have regular appointments with your doctor so they can make sure the treatment is working as it should. You can expect recurring blood tests, urine tests and weight checks. The tests and checks may be able to discover side effects before they develop and become serious.

If you are about to start taking any other medicine while you are using Imatinib, tell your doctor, pharmacist and dentist.

Make sure that all doctors, pharmacists and dentists who are working with you know that you are taking Imatinib.

You should avoid becoming pregnant while you are taking Imatinib. This means using an effective form of birth control, such as oral contraception or intrauterine devices.

Tell your doctor without delay if you or your partner becomes pregnant while you are taking Imatinib treatment.

This medicine has been prescribed for you personally. Do not give it to anyone else even if their symptoms are the same as yours, as it may harm them.

Imatinib should not be used to remedy any conditions other than what your doctor has prescribed it for.

## ***Important advice when taking Imatinib***

### **Do not drink grapefruit juice.**

Grapefruit juice can affect how your body reacts to your treatment with Imatinib.

### **Avoid using medications that contain paracetamol.**

Talk to your pharmacist or doctor for their advice on what other medication you may take when needing medicine to help with a cold, headache or other minor pains.

### **Use sunscreen (at least SPF 15+) and wear protective clothing when you are going outdoors or planning to be in the sun. Sunlamps must be avoided.**

Imatinib can affect how your skin reacts to sunlight, making it more sensitive than usual.

When exposed to the sun, your skin may react with itching, rash, redness or sunburn that is severe. Talk to your doctor if your skin reacts this way.

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## **Side effects**

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Discuss with your doctor or pharmacist any questions or concerns you may have.

All medications can have side effects. For most people who experience side effects they are usually mild and pass after a short time. At times they can be serious and some side effects may require you to have medical treatment.

There can be ways to decrease the severity of these side effects. Your doctor will discuss if you require further medical treatment if you experience some of these side effects.

Do not be concerned by the side effects below. However, if you experience any of the below side effects and they are causing concern, please talk to your doctor or pharmacist:

- Aching, cramping, swelling and/or stiffness in the joints and muscles.
- Altered sense of taste.
- Appetite and weight changes.
- Blurred vision.
- Bone pain or pain along the veins.
- Constipation.
- Cold and/or cough symptoms.
- Diarrhoea.
- Dry mouth.
- Enlargement of breasts, painful periods and nipple pain.
- Eye concerns, such as irritation, itchy, red or runny eyes.
- Feeling anxious, confused, difficulty sleeping, depressed or forgetful.



- Feeling dizzy and/or light-headed.
- Gastrointestinal concerns, such as indigestion, feeling bloated, stomach upset or wind.
- Generally feeling unwell, feeling tired and weak.
- Hair loss.
- Headache.
- Nausea and/or vomiting.
- Night sweats.
- Numbness in fingers and toes, feeling of coldness and/or tingling.
- Ringing in the ears.
- Sexual function problems, loss of interest.
- Skin concerns, such as darkening or lightening of the skin, dry skin, eczema, itching, rash, skin pain, red skin, painful lumps.
- Blisters on skin or mouth, lips, ears, nose).
- Sunburn symptoms, such as blistering skin, itching, redness and/or swelling that occurs more rapidly than normal.
- Swelling and/or reddening of the soles of the feet and palms of the hands. May also have burning pain or tingling sensation.
- Throat pain.
- Vertigo.
- Musculoskeletal pain after stopping Imatinib (including muscle pain, limb pain, joint pain, bone pain and back pain).

**The side effects below can be serious.** If you experience any of these, you may require immediate medical attention. If you experience any of the below, immediately tell your doctor.

- Anaphylactic shock (serious allergic reaction).

**Go to your nearest Accident and Emergency Department at your nearest hospital without delay if you think you are allergic to this medication:**

- Chest pain/tightness of the chest.
- Collapse.
- Difficulty breathing.
- Dizziness or feeling faint.
- Face, lips, tongue, throat swelling which may cause swallowing to become difficult.
- Severe itching of the skin.
- Any abnormal bleeding or nosebleeds.
- Blood in the urine.
- Impaired vision, blood in the eyes and vision that is blurred.
- Indication of cellulitis, for example; skin inflammation triggered by an infection.
- Indication of clots in the blood vessels, for example; pain and swelling in an isolated part of the body.
- Indication of a change of potassium level in the blood, for example; abnormal heart rhythm, muscle spasms and weakness in the muscles.

- Indication of gastrointestinal disorders, for example; abdominal pain that is severe, abdominal swelling or fluid in the abdomen, constipation, pain in the stomach, stools that are bloody or black, vomiting blood.
- Indication of gynaecological disorders, for example; pain in the pelvis that is supplemented with nausea and vomiting and vaginal bleeding that is not expected.
- Indication of heart disorders (angina, heart attack), for example; severe chest pain, fever, irregular heartbeat and tiredness.
- Indication of inflammatory bowel disease, for example; abdominal pain, diarrhoea, fever, nausea and vomiting.
- Indication of liver disorder, for example, appetite loss, nausea, urine that is dark in colour, yellowing of the eyes and skin.
- Indication of low intake of fluids/drinks, for example; loss of weight, thirsty, urine output is severely decreased.
- Indication of low level of blood cells, for example; recurrent infections (with chills, fever, mouth ulcers, sore throat, swollen glands), unplanned bruising or bleeding and weakness.
- Indications of lung disorders or infections, for example; cough, difficulty breathing or breathing that is painful, pain in the chest and wheezing.
- Indication of muscle disorders, for example; fever, kidney disorders, muscle pain or weakness, muscle spasms, urine that is red brown.
- Indication of pressure increase within the skull, for example; blurred vision, dizziness and a severe headache.
- Indication of nervous system disorders (bleeding in the brain/skull or swelling), for example; face or limb paralysis, loss of consciousness that is sudden, severe headache, speaking becomes difficult, weakness.
- Indication of red blood cell break down, for example; breathlessness, pale skin, tiredness and urine that is dark in colour.
- Indication of skin disorders, for example; blistering eyes, lips, mouth or skin, burning, fever, itching, patches of skin that are raised and red or purple, peeling skin, pustular eruption, red skin or severe rash.
- Indication of water retention, for example; general swelling (face swelling) and swelling of the limbs such as the ankles and calves, rapid weight gain.
- Irregular heartbeat, joint soreness, nausea, shortness of breath, urine that is cloudy that are all linked with abnormal laboratory results, for example, in the blood, high potassium, phosphorous levels and uric acid and depleted calcium levels.
- Itching, hives, peeling or blistering skin, severe skin rash, which may present with aching muscles and joints, chills, fever, headache, pain in the stomach and swollen glands.
- Changes in urine or blood in urine, pain in the kidney area, tiredness, loss of appetite, nausea/vomiting, lack of concentration, headache, cramping, itching (signs of kidney disorder).
- Pain and walking difficulty.
- Seizures and/or fits.

- Fever, skin rash, joint pain and swelling as well as tiredness, loss of appetite, nausea, jaundice (yellowing of the skin), pain in the upper right abdomen, pale stools and dark urine (potential signs of hepatitis B reactivation).

If you experience any other side effects that are not discussed above, tell your doctor without delay.

Additional side effects not recorded above may occur in some individuals. Some side effects can only be discovered through testing in the laboratory.

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## **After using Imatinib**

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### ***Storage and disposal***

Keep out of reach of children by storing your Imatinib capsules in a locked cabinet at a height that is hard to reach for children.

**Avoid direct sunlight or heat. Do not store your Imatinib capsules in your car on a hot day or on a windowsill.**

Store Imatinib below 30°C. Protect from light and moisture.

Keep the Imatinib capsules in their pack until you are about to take them.

The expiry date is the last day of the expiry month on the blister foil or pack.

### ***Disposal***

If your doctor advises you to stop taking Imatinib, or they have exceeded their expiry date, request information from your pharmacist on what to do with any product that is left over.

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## **Product description**

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Imatinib 100 mg consists of light-yellow granules in a size 3 hard gelatin capsule with a brown cap and white body.

Imatinib 400 mg consists of light-yellow granules filled in a size 00EL hard gelatin capsule with a brown cap and brown body.

### ***Ingredients***

The active ingredient in an Imatinib capsule contains 100 mg or 400 mg of imatinib.

Each Imatinib capsule also contains lactose anhydrous, crospovidone, silica – colloidal anhydrous and magnesium stearate.

Does not contain gluten.

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## **Sponsor Details**

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### ***NZ Distributor***

REX Medical Limited  
PO Box 18-119  
Glen Innes  
Auckland 1743

[admin@rexmed.co.nz](mailto:admin@rexmed.co.nz)

Ph: (09) 574 6060 | Fax: (09) 574 6070

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## **Date of Preparation**

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