

Imatib Film Coated Tablets

Consumer Medication Information Leaflet (RiMUP)

Imatinib mesilate (100 mg, 400 mg)

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What Imatib is used for

Imatib is a medicine to treat cancer.

Imatib is a treatment for adults and children for:

- Chronic myeloid leukaemia (CML)
- Acute lymphoblastic leukemia (ALL) with Philadelphia chromosome positive (Ph-positive ALL).

Leukaemia is a cancer of white blood cells. These white cells usually help the body to fight infection. CML and ALL are cancers of the blood which makes the body produce too many abnormal white blood cells.

Imatib is also a treatment for adults for:

- Certain types of gastrointestinal stromal tumors (GIST). GIST are cancers of the stomach and the bowels.
- Certain types of dermatofibrosarcoma protuberans (DFSP).

They arise from uncontrolled cell growth.

- Certain types of myelodysplastic/myeloproliferative diseases (MDS/MPD), a group of blood diseases which make the

body produce too many abnormal blood cells.

- Certain types of aggressive systemic mastocytosis (ASM).
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL), blood diseases which make the body produce too many blood cells.

How Imatib works

Imatib works by slowing the growth of abnormal cells. Imatib kills the abnormal cells while leaving normal cells alone in the diseases listed above. If you have any questions about how Imatib works or why this medicine has been prescribed for you, ask your doctor.

Before you use Imatib

Your Imatib treatment will be prescribed by a doctor with experience in the use of anticancer therapies. Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

- When you must not use it

If you are allergic (hypersensitive) to imatinib or any of the other ingredients of this medicine (listed in section Product Description).

If this applies to you, tell your doctor without taking Imatib. If you think you may be allergic, ask your doctor for advice.

Pregnancy and breast-feeding

Imatib is not recommended during pregnancy unless clearly necessary as it may harm your baby. If you are pregnant or think you may be, tell your doctor, who will discuss with

you the potential risk of taking Imatib during pregnancy.

You should not breast-feed while taking Imatib and for 15 days after the last dose, as it may harm your baby. Tell your doctor if you are breast-feeding.

Females of child-bearing potential and male patients

Females of child-bearing potential must use effective birth control while taking Imatib and for 15 days after ending treatment. Male patients concerned about their ability to father children while on Imatib treatment should consult with their physician.

- Before you start to use it

Before taking Imatib, tell your doctor:

- If you have a liver, kidney or heart problem, or used to have one.
- If you are receiving treatment with levothyroxine because your thyroid has been removed.
- If you have ever had or might now have a hepatitis B infection. This is because during treatment with Imatib, hepatitis B may become active again. Your doctor will check for signs of this infection before treatment with Imatib is started.
- If you experience bruising, bleeding, fever, fatigue and confusion when taking Imatib. This may be a sign of damage of blood vessels known as thrombotic microangiopathy (TMA).

Older people (65 years and over)

Imatib can be used by people over the age of 65 at the same dose as other adults.

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Children

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

- Taking other medicines

Imatib may interfere with some other medicines.

Before taking Imatib, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- some medicines used to treat infections such as ketoconazole, itraconazole, erythromycin, or clarithromycin,
- some medicines used to treat epilepsy such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, fosphenytoin, or primidone,
- some medicines used to treat high cholesterol such as simvastatin,
- some medicines used to treat mental disorders such as benzodiazepines or pimozone,
- some medicines used to treat high blood pressure or heart disorders such as calcium channel blockers or metoprolol,
- rifampicin, a medicine used to treat tuberculosis,
- St. John's Wort - a herbal product used to treat depression and other conditions (also known as *Hypericum Perforatum*),
- dexamethasone, an anti-inflammatory medicine,
- cyclosporine, an immunosuppressant medicine,
- warfarin, a medicine used to treat blood clot disorders.

These medications should be avoided during your treatment with Imatib. If you are taking any of these, your

doctor might prescribe other alternative medicines.

You should also tell your doctor if you are already taking Imatib and you are prescribed a new medicine, including medicines obtained without prescription, you have not taken previously during Imatib treatment.

How to use Imatib

Follow instructions carefully and always take Imatib exactly as your doctor has told you. Do not exceed the recommended dose.

- How much to use

Adults

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

- If you are being treated for CML or GIST: depending on your condition, the usual starting dose is:
 - either 400 mg to be taken once a day,
 - or 600 mg to be taken once a day
 - 400mg to be taken twice a day
- If you are being treated for Ph-positive ALL: the starting dose is 600 mg to be taken once a day.
- If you are being treated for MDS/MPD: the starting dose is 400 mg, to be taken once a day.
- If you are being treated for DFSP: the starting dose is 800 mg per day.
- If you are being treated for ASM or HES/CEL: the usual starting dose is 400 mg, to be taken once a day.
- For some conditions, the starting dose is 100 mg once a day.

Your doctor may decide to increase the dose to 400 mg once a day

depending on how you respond to treatment.

How to take the medicine:

400 mg to be taken as one tablet of 400 mg once a day;

600 mg to be taken as one tablet of 400mg plus 2 tablets of 100 mg once a day;

600 mg to be taken as one tablet of 400 mg plus half a 400 mg divisible tablet;

800 mg to be taken as one tablet of 400 mg in the morning and a second tablet of 400 mg in the evening.

Children

The doctor will tell you how many tablets to give your child. The amount of Imatib given will depend on your child's condition, and also his or her body weight and height.

The total daily dose in children must not exceed 600 mg daily.

The treatment for CML can either be given to your child as a once-daily dose or alternatively the daily dose can be split into two administrations (one in the morning and one in the evening).

The treatment for ALL can be given to your child as a once-daily dose.

There is no experience with the use of Glivec in children with CML below 2 years of age and with Ph+ALL below 1 year of age.

- When to use it

Take Imatib with a meal as this will help to protect your stomach.

Swallow the whole tablet with a large glass of water.

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Film-coated tablets

If you are unable to swallow the tablets, you can stir them into a glass of water or apple juice:

- Put the required tablets(s) in a sufficient quantity of liquid (approximately 50 ml for a 100 mg tablet and 200 ml for a 400 mg tablet).
- Stir with a spoon until the tablets have completely dissolved.
- Immediately drink the whole contents of the glass.

- How long to use it

Take Imatib daily until your doctor tells you to stop. Make sure you take Imatib for as long as it is prescribed.

- If you forget to use it

If a dose is missed or vomiting occurs, do not make up the dose. Instead wait until it is time for your next dose.

- If you use too much (overdose)

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 nausea, vomiting, diarrhea, rash, swelling, fatigue, muscle spasms, abdominal pain.

While you are using Imatib

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not stop taking your medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

If you experience symptoms, like dizziness or drowsiness, or if you have blurred vision while taking Imatib, do not drive a vehicle or operate any tools or machines until you are feeling well again.

Monitoring during your treatment with Imatib

Your doctor will regularly monitor your condition to check whether Imatib is having the desired effect. You will also have regular blood tests to see how Imatib is tolerated (e.g. blood cells, liver, thyroid and kidney function). You will need to have your weight measured regularly.

Side effects

As with all medicines, people treated with Imatib may experience side effects, although not everybody gets them. Most of the side effects are mild to moderate.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Very common to common:

Rapid weight gain, swelling of extremities (calves, ankles), generalized swelling such as swelling of the face (signs of water retention).

- Weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of low level of blood cells).

- Severe abdominal pain, vomiting blood, finding blood in your stools, or having black stools (signs of gastrointestinal bleeding).
- Nausea, shortness of breath

Uncommon to rare:

Abnormal laboratory values (such as high potassium, uric acid)

- Pain in bone or joints (signs of osteonecrosis) and inflammation 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).
- Irregular heartbeat
- blood clots in small blood vessels (thrombotic microangiopathy)

Unknown frequency

- Fever, skin rash

Other possible side effects

Tell your doctor if any of the side effects listed below affects you severely.

- Unable to sleep
- Headache, dizziness, tingling, pain or numbness of the hands, feet, legs or around the hip, taste disturbance, decreased skin sensitivity
- swelling of the eyelids or around the eye, discharge from the eye with redness and itching eye (conjunctivitis), increased tear production, dry eye
- hot flushes
- nose bleeds,
- indigestion, dry mouth, heartburn, swelling in the abdomen, flatulence, constipation
- itchy/red/burning rash, dry skin, unusual hair loss or thinning,

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- night sweats, increased sensitivity of the skin to sun (sign of photosensitivity)
- muscle cramps, fatigue
- musculoskeletal pain after discontinuing treatment with Imatib (including muscle pain, limb pain, joint pain, bone pain and back pain)
- painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin; signs of panniculitis)
- blisters on skin or mucous membranes (signs of pemphigus)

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist or health care provider.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers ->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Imatib

- Storage

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 bottle, blister or carton after EXP. That expiry date refers to the last day of that month.

Store below 30 °C. Protect from moisture. Store in original packaging.

- Disposal

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

Product Description

- What it looks like

Imatib 100 mg Film Coated Tablets

Very dark yellow to brownish orange, film coated tablets, round, biconvex with bevelled edges, debossed with "C211" on one side with score on other side.

Imatib 400 mg Film Coated Tablets

Very dark yellow to brownish orange, film coated tablets, Ovaloid, biconvex with bevelled edges, debossed with "C212" on one side with score on other side.

- Ingredients

Active ingredient:

- Imatinib

Inactive ingredient:

- Hypromellose
- Microcrystalline Cellulose
- Crospovidone
- Colloidal Silicon Dioxide
- Magnesium Stearate
- Opadry Yellow 03f520229
- Titanium Dioxide
- Purified Water

- MAL Number

Imatib 100 mg Film Coated Tablets

MAL22126037AZ

Imatib 400 mg Film Coated Tablets

MAL22126038AZ

Manufacturer

CIPLA LTD

S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A Verna Industrial Estate, Verna, Goa, India.

Product Registration Holder

CIPLA MALAYSIA SDN BHD

Suite 1101, Amcorp Tower, Amcorp Trade Centre, 18 Persiaran Barat, 46050 Petaling Jaya, Selangor, Malaysia.

Date of Revision

14/02/2024

Serial Number

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