

IMATERO 100 (Imatinib Tablet 100mg)

IMATERO 400 (Imatinib Tablet 400mg)

Imatinib Mesylate (100mg/400mg)

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What IMATERO is used for

IMATERO is a medicine to treat cancer.

IMATERO is a treatment for adults and children for:

- chronic myeloid leukaemia (CML).
- acute lymphoblastic leukaemia (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

IMATERO is also a treatment for adults for:

- certain types of gastrointestinal stromal tumours (GIST). GIST is a cancer of the stomach and 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 leukemia (CEL), blood diseases

which make the body produce too many blood cells.

How IMATERO works

IMATERO works by slowing the growth of abnormal cells. IMATERO kills the abnormal cells while leaving normal cells alone in the diseases listed above.

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

Before you use IMATERO

Your IMATERO 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 IMATERO listed at the end of this leaflet. If this applies to you, tell your doctor without taking IMATERO.

If you think you may be allergic, ask your doctor for advice.

Pregnancy and breast-feeding

IMATERO 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 IMATERO during pregnancy.

You should not breast-feed while taking IMATERO 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 IMATERO and for 15 days after ending treatment. Male patients concerned about their ability to father children while on

IMATERO treatment should consult with their physician.

-Before you start to use it

Before taking IMATERO, 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 IMATERO, hepatitis B may become active again. Your doctor will check for signs of this infection before treatment with IMATERO is started.
- If you experience bruising, bleeding, fever, fatigue and confusion when taking IMATERO. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).

Older people (65 years or above)

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

Children

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

-Taking other medicines

IMATERO may interfere with some other medicines.

Before taking IMATERO, 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,

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- some medicines used to treat high cholesterol such as simvastatin,
- some medicines used to treat mental disorders such as benzodiazepines or pimozide,
- 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 IMATERO. 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 IMATERO and you are prescribed a new medicine, including medicines obtained without prescription, you have not taken previously during IMATERO treatment.

How to use IMATERO

Follow instruction carefully and always take IMATERO 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 IMATERO 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,
- 400 mg 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 DESP:

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 400mg 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 IMATERO 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 IMATERO in children with CML below 2 years of age and with Ph+ALL below 1 year of age.

-When to use it:

Take IMATERO with a meal as this will help to protect your stomach. Swallow the tablets whole with a large glass of water.

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 tablet(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 to completely disintegrate the tablet(s).
- Immediately drink the whole contents of the glass.

-How long to use it:

Take IMATERO daily until your doctor tells you to stop. Make sure you take IMATERO 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 immediately. You may require medical attention.

Sign and symptoms of overdosage include: nausea, vomiting, diarrhea, rash, swelling, fatigue, muscle spasms, abdominal pain.

While you are using IMATERO

-Things you must do

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Take your medicine exactly as your doctor has told you.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

-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 IMATERO, do not drive a vehicle or operate any tools or machines until you feeling well again.

Monitoring during your treatment with IMATERO

Your doctor will regularly monitor your condition to check whether IMATERO is having the desired effect. You will also have regular blood tests to see how IMATERO 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 IMATERO 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 effects could be serious

Tell your doctor immediately if you experience any of the side effects listed below.

Very common to common: may affect more than 1 in 10 people

- 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 very rare: may affect up to 1 in every 100 people

- 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, night sweats, increased sensitivity of the skin to sun (sign of photosensitivity)
- muscle cramps, fatigue

- musculoskeletal pain after discontinuing treatment with IMATERO (including muscle pain, limb pain, joint pain, bone pain and back pain)
- 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 IMATERO

-Storage

Store below 30°C. Store in the original package. Protect from moisture. Keep out of the reach and sight of children.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

IMATERO 100 (Imatinib Tablet 100 mg): White to off white coloured, round, bevel edged scored tablets debossed with 'H' on one side and '19' on the other side, '1' and '9' separated by a score line.

IMATERO 400 (Imatinib Tablet 400 mg): White to off white coloured, capsule shaped, bevel edged scored tablets, debossed with 'H' on one side and '20' on the other side, '2' and '0' separated by a score line.

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Pack size:

IMATERO 100: 6 x 10s

IMATERO 400: 3 x 10s

-Ingredients

- *Active ingredient*

Imatinib Mesylate

- *Inactive ingredients*

Magnesium Stearate, Opadry White

03F58763 (Composition:

Hypromellose (2910), Titanium

dioxide (E171), Macrogol (E1521),

Talc (E553b))

MAL number:

IMATERO 100: MAL23086008AZ

IMATERO 400: MAL23086007AZ

Manufacturer

Hetero Labs Limited,

Unit – VI, Sy.No.410-411,

TSIIC Formulation SEZ,

Polepally Village, Jadcherla (Mandal),

Mahaboob Nagar (District), Pin-509301,

Telangana, INDIA.

Product Registration Holder

Camber Laboratories Sdn. Bhd.

Unit E-13A-02, Menara SUEZCAP 2,

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59200 Kuala Lumpur, Malaysia.

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10/02/2025

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