

IMAMED 100 & 400

Imatinib Mesylate Tablets 100mg / Imatinib Mesylate Tablets 400mg

What is in this leaflet

1. What IMAMED is used for
2. How IMAMED works
3. Before you use IMAMED
4. How to use IMAMED
5. While you are using it
6. Side effects
7. Storage and Disposal of IMAMED
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What IMAMED is used for

IMAMED 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 blood cells usually help the body to fight infection. Acute lymphoblastic leukaemia in which certain abnormal white blood cells (named lymphoblasts) start growing out of control. Imatinib inhibits the growth of these cells.

IMAMED 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.

- **Gastrointestinal stromal tumours (GIST).** GIST is a cancer of the stomach and bowels. It arises from uncontrolled cell growth of the supporting tissues of these organs.
- **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.
- **Aggressive systemic mastocytosis (ASM).** ASM is a severe and rare form of systemic mastocytosis (SM) characterized by considerable infiltration of mast cells in different tissues.

How IMAMED works

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

Before you use IMAMED

• When you must not use it

Do not take IMAMED if you are hypersensitive to Imatinib mesylate or any other ingredients in the product.

If you are breastfeeding

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

• Before you start to use it

Discuss with your doctor or pharmacist if:

- You have liver, kidney or heart problem.
- You are taking medicine containing levothyroxine because your thyroid has been removed.
- You have ever had or might have hepatitis B infection.
- Older people (65 years or above): IMAMED can be used by people over the age of 65 at the same dose as other adults.
- Children: Some children taking IMAMED may have slower than

normal growth. The doctor will monitor the growth at regular visits.

Before taking IMAMED, tell your doctor:

- if you experience bruising, bleeding, fever, fatigue and confusion when taking IMAMED. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).

Pregnancy, breastfeeding and fertility

Ask your doctor or pharmacist for advice before taking IMAMED if you are pregnant, trying to get pregnant or think you may be pregnant or if you are breastfeeding.

IMAMED 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 IMAMED during pregnancy.

Women of childbearing potential must be advised to use effective contraception during treatment and for at least 15 days after stopping treatment with IMAMED.

You should not breast-feed during treatment and for at least 15 days after stopping treatment with IMAMED.

Patients concerned about their fertility on IMAMED treatment should consult with their physician.

• Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are particularly taking:

- 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.

How to use IMAMED

IMAMED is for oral use. The prescribed dose should be administered orally with a meal and a large glass of water to minimise the risk of gastrointestinal irritations.

• How much to use

- 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.

Adults

Your doctor will tell you exactly how many tablets of IMAMED 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 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.
- When to use it
Use as directed by your doctor or pharmacist.

• How long to use it

Continue taking IMAMED for as long as your doctor recommends.

• 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)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, diarrhoea, rash, skin redness, swelling, fatigue, muscle cramps, abdominal pain, headache, decreased appetite, weakness, muscle ache, stomach pain, fever and facial swelling

While you are using it

• Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking IMAMED.

Tell your doctor immediately if you become pregnant while taking this medication.

• Things you must not do

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

Do not take any new medicines without consulting your doctor.

Do not give IMAMED to anyone else, even if they have the same symptoms or condition as you.

• Things to be careful of

You should not breastfeed during treatment with IMAMED.

Weight should be monitored regularly.

Driving and using machines

This medicine may affect your ability to drive or use machines. You may experience dizziness, blurred vision or somnolence. If you have any of these side effects, do not drive or use any tools or machines.

Side effects

Like all medicines, IMAMED can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common or common side effects

- low red blood cell count (anaemia), low white blood cell count (neutropenia), low blood platelet count (thrombocytopenia), low blood cell count (pancytopenia)
- abnormal loss of appetite for food (anorexia)
- inability to sleep (insomnia)
- headache, dizziness, paraesthesia (abnormal sensation of skin), taste disturbance, hypoaesthesia (abnormal sensory response)
- swollen eyelid, increased lacrimation (secretion of tears), bleeding of conjunctiva (mucous membrane of eye), conjunctivitis, dry eye, blurred vision

- reddening of skin, bleeding
- shortness of breath, nosebleeds, cough
- nausea, diarrhoea, vomiting, indigestion, abdominal pain, constipation, dry mouth, farting, acid reflux
- increased hepatic enzyme
- rash, swelling around the eyes (periorbital oedema), itchy skin, face swelling, dry skin, skin redness, alopecia (condition caused hair to fall out), night sweats, photosensitivity reaction
- joint swelling
- Muscle ache, muscle cramps, bone pain
- fluid retention in the body (oedema), fatigue, weakness, fever, anasarca (body swelling), feeling cold
- weight increased and decreased

Uncommon or rare side effects

- chest pain
- cough, difficult to breath
- feeling light headed, dizzy or fainting
- nausea, loss of appetite, dark colored urine, yellow skin (jaundice)
- rash, red skin with blisters on the lips, eyes
- abdominal pain
- decreased urine output, feeling thirsty
- weakness or paralysis of limbs or face
- pale skin, feeling tired and breathlessness
- eye pain or deterioration in vision
- difficulty breathing
- Blood disorders
- Renal disorders
- Depression, libido decreased, anxiety
- erectile dysfunction, menstruation irregular, sexual dysfunction, nipple pain, breast enlargement, scrotal swell
- blood clots in small blood vessels (thrombotic microangiopathy).

Not known side effects

- hepatitis B reactivation
- bleeding tumour
- anaphylactic shock (severe allergic reaction)

- brain oedema (fluid retention in brain)
- vitreous haemorrhage (presence of blood at the back part of eye)
- pericarditis (inflammation of heart tissue), cardiac tamponade (heart disease)
- thrombosis/embolism (blood clot in blood vessel)
- acute respiratory failure
- intestinal obstruction, diverticulitis (inflammation of pouches in intestine), gastric antral vascular ectasia (GAVE) (uncommon cause of gastrointestinal bleeding)
- hand-foot syndrome (redness, swelling and pain on palm of hands or soles of feet), lichenoid keratosis (skin condition), lichen planus (inflammatory skin condition), toxic epidermal necrolysis (type of severe skin reaction)
- avascular necrosis/hip necrosis (death of bone tissue due to a lack of blood supply), slowing growth in children
- chronic renal failure

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

Storage and Disposal of IMAMED

- *Storage*

Keep out of the reach and sight of children.

Store below 30°C.

Protect from moisture.

Store in original package.

- *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*

IMAMED 400- Imatinib Mesylate Tablets 400 mg

Dark yellow to brownish orange colored, film coated tablets, capsule shaped, biconvex with bevelled edges debossed with 'S' and '2' on either side of break line on one side and plain on other side.

IMAMED 100-Imatinib Mesylate Tablets 100

Dark yellow to brownish orange colored, film coated tablets, round, biconvex with bevelled edges debossed with 'S' and '1' on either side of break line on one side and plain on other side.

- *Ingredients*

- Active ingredient(s)
Imatinib Mesylate

- Inactive ingredients
Providone K-30, Magnesium Stearate, Opadry Brown.

- *MAL number(s):*

IMAMED 100-Imatinib Mesylate Tablets 100

MAL23016010ACZ

IMAMED 400- Imatinib Mesylate Tablets 400 mg

MAL23016011ACZ

Manufacturer

Shilpa Medicare Limited
Unit 4, Pharmaceutical Formulations SEZ, Plot No's S-20 to S-26, Pharma SEZ, TSIIC, Green Industrial Park, Polepally (V), Jadcherla (M), Mahabubnagar (Dt), 509301 Telangana, India.

Product Registration Holder

Unimed Sdn Bhd
53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara 52200, Kuala Lumpur, Malaysia.

Date of revision

02/02/2024

Serial Number

NPRA(R2/1)240306/1220