

IMINOX TABLET

Imatinib (100 mg, 400 mg)

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What IMINOX is used for

IMINOX 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 them 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.

IMINOX 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 IMINOX works

IMINOX contains imatinib. This medicine works by inhibiting the growth of abnormal cells in the diseases as listed above. These include some types of cancer.

Before you use IMINOX

- When you must not use it

If allergic (hypersensitive) to the imatinib or to any of the other ingredients of IMINOX.

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.

Before taking IMINOX, tell your doctor:

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

Pregnancy and lactation

Do not take IMINOX if you are pregnant or think you may be pregnant. Imatinib should not be used during pregnancy unless clearly necessary. If it used during pregnancy, the patient must be informed of the potential risk to the foetus.

Women who might become pregnant are advised to use contraception during treatment and for at least 15 days after stopping treatment with IMINOX.

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

If you concerned about fertility on IMINOX treatment, ask your doctor or

pharmacist for advice before taking any medicine.

Driving and use 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.

- Taking other medicines

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

Tell your doctor if you are taking:

- Protease inhibitors – Indinavir, lopinavir/ritonavir, saquinavir, telaprevir, nelfinavir, boceprevir
- Azole antifungals – Ketoconazole, itraconazole, posaconazole, voriconazole
- Macrolides – erythromycin, clarithromycin, telithromycin
- Substances that induce CYP3A4 activity – Dexamethasone, phenytoin, carbamazepine, rifampicin, phenobarbital, fosphenytoin, primidone, *Hypericum perforatum* (St. John's Wort)
- CYP3A4 substrates with a narrow therapeutic window – Cyclosporine, pimezone, tacrolimus, sirolimus, ergotamine, diergotamine, fentanyl, alfentanil, terfenadine, borteomib, docetaxel, quinidine
- CYP3A4 metabolized drugs – Triazolo-benzodiazepines, dihydropyridine calcium channel blockers, statins
- Coumarin derivatives – Warfarin
- CYP2D6 substrates with a narrow therapeutic window – Metoprolol
- Paracetamol (common painkiller)
- Levothyroxine (medicine to treat hypothyroidism)
- Chemotherapy drug

How to use IMINOX

- How much to use

Follow all instructions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking IMINOX for as long as your doctor or pharmacist recommends.

- If you forget to use it

It is important not to miss a dose of this medicine.

If you do miss a dose:

- and you notice within 18 hours of the time you usually take IMINOX, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- and you notice 18 hours or more after the time you usually take IMINOX, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

- If you use too much (overdose)

Symptoms of overdose include:

- Adults: Nausea, vomiting, diarrhoea, rash, erythema (skin reddening), oedema (fluid retention in the body), swelling, fatigue, muscle cramp, thrombocytopenia (low blood platelet count), pancytopenia (low blood cell count), abdominal pain, headache, decreased appetite, weakness, myalgia (muscle pain), increased bilirubin (yellowish substance in blood) and creatinine phosphokinase (body enzyme), gastrointestinal pain, pyrexia (fever), facial swelling, decreased white blood cell count, increased transaminases (body enzyme).
- Children: Vomiting, diarrhoea, anorexia, decreased white blood cell count.

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.

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 IMINOX.

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 IMINOX 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 IMINOX.

Weight should be monitored regularly.

Side effects

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

Tell 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
- 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 breathe
- 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 clots in small blood vessels (thrombotic microangiopathy)

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

- 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

If any of the side effects gets serious, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction

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Monitoring by visiting the website nppra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of IMINOX

- Storage

Keep medicine out of reach 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

IMINOX TABLET 100MG

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

IMINOX TABLET 400MG

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

- Ingredients

- Active ingredient(s)

IMINOX TABLET 100MG Imatinib
100mg

IMINOX TABLET 400MG

Imatinib 400mg

- Inactive ingredients

Povidone K-30 (Plasdone K-29/32),
Magnesium Stearate, Opadry Brown
02F86982

- MAL number:

IMINOX TABLET 100MG
MAL22016012AZ

IMINOX TABLET 400MG

MAL22016013AZ

Manufacturer

Shilpa Medicare Limited
Plot No. S-20 to S-26, Pharma SEZ,
TSIIC, Green Industrial Park, Polepally
Village, Jadcherla Mandal, Mahabubnagar
District, 509301, Telangana, India

Product Registration Holder

InspiraPharma Sdn. Bhd.
Lot 24 & 25, Jalan 8,
Kawasan Perusahaan Bakar Arang,
08000 Sungai Petani,
Kedah Darul Aman, Malaysia

Date of Revision

11/02/2026

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