

APO-IMATINIB TABLETS

Consumer Medication Information Leaflet (RiMUP)

Imatinib Mesylate (100mg, 400mg)

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What Apo-Imatinib is used for

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

Apo-Imatinib 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. Apo-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. Apo-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. Apo-Imatinib inhibits the growth of these cells.

How Apo-Imatinib works

Apo-Imatinib is a medicine containing an active substance called imatinib. This medicine works by inhibiting the growth of abnormal cells in the diseases mentioned above.

Before you use Apo-Imatinib

- When you must not use it

Do not use this medication if you are allergic to Imatinib Mesylate or any other ingredients in this medication. (Refer to **Product Description**)

Pregnancy and lactation

Do not take Apo-Imatinib if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Imatinib if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Before using this product, your doctor should know any other medical condition you have, including liver, kidney disease, and/or any heart disease.

- 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.

Some medication will cause complications when taken together with Apo-Imatinib, such as:

- CYP3A4 inhibitors (e.g. protease inhibitors such as indinavir,; azole antifungals including ketoconazole,; certain macrolides such as erythromycin) might cause decreased metabolism and increased imatinib concentration in the body.

- Inducers of CYP3A4 activity (e.g. dexamethasone, phenytoin, or St. John's Wort) may significantly reduce exposure to Apo-Imatinib, potentially increasing the risk of Imatinib to lose its efficacy.

- Narrow therapeutic medications (e.g. cyclosporine, pimozide), where Imatinib might increase the plasma level of these medications.

- Warfarin, as it may cause the increase in risk of bleeding.

- Paracetamol

- Levothyroxine, as Imatinib might cause this medication to reduce its effectiveness.

How to use Apo-Imatinib

- How much to use

Follow all directions given to you by your doctor and 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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Apo-Imatinib for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed 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.

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 Apo-Imatinib.

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 Apo-Imatinib to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or

use machines and contact your doctor immediately.

Side effects

Like all medicines, Apo-Imatinib can cause side effects, although not everybody gets them.

The following are side effects that occur very commonly or commonly:

Very Common: Neutropenia (Low white blood cell count), thrombocytopenia (Low platelet count), anemia (low in red Blood cell Count), headache, nausea, diarrhea, vomiting, dyspepsia (uncomfortable feeling in the upper middle of the stomach), abdominal pain, periorbital oedema (swelling of the eyes), dermatitis/eczema/rash, muscle spasm and cramps, musculoskeletal pain including myalgia (muscle pain), arthralgia (joint pain), bone pain, fluid retention and oedema, fatigue, or weight increased

Common: Pancytopenia (deficiency of all three red, white and platelet cells), febrile neutropenia (fever due to low white blood cells), anorexia, insomnia, dizziness, paraesthesia (abnormal sensation), taste disturbance, hypoesthesia (reduced sense of touch), eyelid oedema, lacrimation (flow of tears) increased, conjunctival haemorrhage (eyes become red), conjunctivitis (eyes irritation), dry eye, blurred vision, flushing, haemorrhage, dyspnea (difficulties breathing), epistaxis (nose bleeding), cough, flatulence, abdominal distension, gastro-oesophageal reflux, constipation, dry mouth, gastritis, increased hepatic enzymes, pruritus (itchiness of the skin), face oedema, dry skin, erythema (reddened skin), alopecia (hair loss), night sweats, photosensitivity reaction, joint swelling, weakness, pyrexia (raised body temperature/fever), anasarca (swelling of the skin), chills, rigors, weight decreased.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <http://npra.moh.gov.my/> (Consumers → Reporting).

Storage and Disposal of Apo-Imatinib

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- 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

100 mg: Brownish orange, round biconvex, beveled-edge film-coated tablets. Engraved "IMA" over score "100" on one side, "APO" on the other side.

400 mg: Brownish orange, capsule shaped, biconvex film-coated tablets. Engraved "IMA" score "400" on one side, "APO" on the other side.

- Ingredients

- Active ingredient:
Imatinib Mesylate

- Inactive ingredients:
Core Tablets: Crospovidone, Magnesium Stearate, Colloidal Silicon Dioxide

Film coating: Hydroxypropyl Methyl cellulose 2910 E5, Hydroxypropyl Cellulose, Polyethylene Glycol 8000, Red

Ferric Oxide, Yellow Ferric Oxide,
Purified Water.

- *MAL numbers:*

Apo-Imatinib 100mg:
MALXXXXXXXXXXXX

Apo-Imatinib 400mg:
MALXXXXXXXXXXXX

Manufacturer

Apotex Inc,
150 Signet Drive, Weston,
Ontario, Canada
M9L IT9

Product Registration Holder

Pharmaforte(M) Sdn Bhd
2, Jalan PJU 3/49, Sunway Damansara,
47810 Petaling Jaya,
Selangor.

Date of revision

18/8/2017

Serial Number

BPFK (Rx/x)xxxxxx/xxxxx