

IMAREM FILM COATED TABLETS

Imatinib (100mg and 400mg)

What is in this leaflet

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

What Imarem is used for

Imarem is used in the treatment for adult and children for:

- Chronic myeloid leukemia (CML) as well as for the treatment for CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

[Leukaemia is cancer of white blood cells. Chronic myeloid leukemia is a form of leukaemia in which certain abnormal white cells (myeloid cells) start growing out of control]

- Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. [Acute lymphoblastic leukaemia is a form of leukaemia in which certain abnormal white cells (named lymphoblasts) start growing out of control].

Imarem is also used in the treatment for adult for:

- Certain types of gastrointestinal stromal tumors (GIST). GIST are cancers of the stomach and the bowels.
- Relapsed or refractory Ph+ ALL as monotherapy.
- Myelodysplastic/myeloproliferative diseases (MDS/MPD). These are a group of blood disease in which some blood cells start growing out of control.
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia

(CEL) with FIP1L1-PDGFR α re-arrangement. These are blood diseases in which some blood cells named eosinophils start growing out of controls.

- Dermatofibrosarcoma protuberans (DFSP). DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control.
- Aggressive systemic mastocytosis (ASM). ASM is a rare condition where certain white blood cells (mast cells) build up in certain tissue and organs in the body.

How Imarem works

Imarem is a medicine containing an active substance called *imatinib*. This medicine works by inhibiting the growth of abnormal cells in some types of cancer, this include Ph+ CML.

Before you use Imarem

- When you must not use it

If you are allergic to *imatinib* or any of the other ingredients of this medicine listed in the 'inactive ingredient' below.

- Before you start to use it

Tell your doctor if you:

-Have or have ever had a liver, kidney or heart problem.

-Are taking the medicine levothyroxine because your thyroid has been removed.

-Have ever had or might now have a hepatitis B infection.

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

- Are pregnant or breastfeeding.

Imarem is not recommended during pregnancy unless clearly necessary as it may harm your baby. Women who might become pregnant are advised to use effective contraception during treatment.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken

any other medicines, including medicines obtained without a prescription. Especially St. John's Wort. Some medicines can interfere with the effect of Imarem when taken together. They may increase or decrease the effect of Imarem, either leading to increased side effects or making Imarem less effective.

Imarem may do the same to some other medicines.

How to use Imarem

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

- How much to use

Adults

- **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:

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

- When to use it

Take Imarem with a meal. This will help protect you from stomach upset.

Swallow the whole tablet with a large glass of water.

If you are unable to swallow the tablets, you can dissolve them in a glass of still water or apple juice:

-Use about 50 ml for each 100 mg tablet or 200 ml for each 400 mg tablet.

-Stir with a spoon until the tablets have completely dissolved.

-Once the tablet has dissolved, drink everything in the glass straight away.

Traces of the dissolved tablets may be left behind in the glass.

The tablet can be divided into equal doses.

- How long to use it

Keep taking Imarem every day for as long as your doctor tells you.

- If you forget to use it

If you forget a dose, take it as soon as you remember. However if it is nearly time for the next dose, skip the missed dose. Then continue with your normal schedule. Do not take a double dose to make up a forgotten 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 including feeling sick, being sick, diarrhea, rash, red skin, tiredness, uncontrollable movements, muscle pain, stomach pain, headache, decreased appetite and weakness.

While you are using it

- Things you must do

During treatment with Imarem, tell your doctor straight away if you put on weight very quickly. Imarem may cause your body to retain water (severe fluid retention).

While you are taking Imarem, your doctor will regularly check whether the medicine is working. You will have blood tests and be weighed regularly.

- Things you must not do

- Do not stop taking your medicines without consulting your doctor.

- Do not use Imarem after the expiry date which is stated on the carton and bottle.

- 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:

This medicine may cause drowsiness and sleepiness, make sure you are not affected before you drive or operate machinery.

Side effects

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

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

Very Common:

Neutropenia (low count of certain type of white blood cell), thrombocytopenia (low blood platelet count), anemia, headache, nausea, diarrhea, vomiting, abdominal pain, rash, muscle cramps, fatigue, increase in weight.

Common:

Pancytopenia (low count for all three blood cells), anorexia, insomnia, dizziness, dry eye, blurred vision, oedema on eyelid, hemorrhage, cough, bloating, constipation, dry mouth, heartburn, dry skin, joint swelling, chills, decreased weight.

Rare:

Blood clots in small blood vessels (thrombotic microangiopathy).

For further information, consult your doctor.

If you get any of the above, tell your doctor straight away.

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.moh.gov.my [Consumers →

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Imatinib (100mg and 400mg)

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Imarem 100mg: MAL20016150ARZ
Imarem 400 mg: MAL20016151ARZ

Storage and Disposal of Imarem

- Storage

Keep out of the reach and sight of children.

Do not store above 30 °C.

Protect from moisture.

Store in the 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

Imarem, 100mg: Dark yellow to brownish-orange, round shaped, film-coated tablets with a breakline on one side and '100' on the other side.

Imarem, 400mg: Dark yellow to brownish-orange, ovaloid shaped, film-coated tablets with a breakline on one side and '400' on the other side.

- Ingredients

- Active ingredient(s)

Imatinib (as mesilate) 100mg

Imatinib (as mesilate) 400mg

- Inactive ingredients

Microcrystalline cellulose (E460),
Low Substituted Hydroxypropyl Cellulose (E463), Povidone (E1201),
Crospovidone (Type A) (E1201),
Silica colloidal anhydrous,
Magnesium Stearate (E572),
Hypromellose (E464),
Macrogol 400, Talc (E553b),
Red Iron Oxide (E172),
Yellow Iron Oxide (E172).

- MAL number:

Manufacturer

Remedica Ltd,
Aharnon Str., Limassol Industrial Estate,
3056 Limassol, Cyprus

Product Registration Holder

Eucogen Sdn. Bhd.
No. 6A, Jalan Sungai Burung
U32/U, Bukit Rimau,
Seksyen 32, 40460 Shah Alam

Date of revision

03/2025

Serial Number

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