

ACCORD IMATINIB TABLET

Imatinib (100mg & 400mg)

What is in this leaflet

1. What Accord Imatinib tablet is used for
2. How Accord Imatinib tablet works
3. Before you use Accord Imatinib tablet
4. How to take Accord Imatinib tablet
5. While you are using Accord Imatinib tablet
6. Side effects
7. Storage and disposal of Accord Imatinib tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Accord Imatinib is used for

Accord Imatinib is indicated in treatment of some types of cancer.

Accord Imatinib is a treatment for adults and children and adolescents 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.
In adult patients, it is intended for use in the most advanced phase of the disease (blast crisis). In children and adolescents, it can be used in different phases of the disease (chronic, accelerated phase and blast crisis).
- 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. Accord Imatinib inhibits the growth of these cells.

Accord Imatinib is 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. Accord 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. Accord 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. Accord 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 Accord Imatinib works

Accord Imatinib contains the active ingredient called 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 Accord Imatinib

- When you must not take it

Do not take Accord Imatinib if you are allergic (hypersensitive) to Imatinib or any of the other ingredients of Imatinib tablets 100 or 400 mg.

- Before you start to take it

Tell your doctor if you have or have ever had a liver, kidney or heart problem.

Before taking Imatinib, tell your doctor:

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

- Taking other medicines

Tell your doctor if you are taking the medicine levothyroxine because your thyroid has been removed.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (such as paracetamol) and including herbal medicines (such as St. John's Wort).

- Taking Imatinib Tablets with food and drink

You can take Imatinib with food. This will help protect you from stomach problems

You can swallow the tablets whole with a large glass of water or dissolved in 50 ml water for each 100 mg tablet.

- Pregnancy and breast-feeding

If you are pregnant or breast-feeding or think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Imatinib is not recommended during pregnancy unless clearly necessary as it may harm your baby. Your doctor will discuss with you the possible risks of taking Imatinib during pregnancy.

Women who might become pregnant are advised to use effective contraception during treatment.

Do not breast-feed during the treatment with Imatinib.

How to use Accord Imatinib

- How much to take:

Your doctor will tell you exactly how many tablets of Accord Imatinib to take.

If you are being treated for

CML:

Depending on your condition the usual starting dose is either 400 mg or 600 mg. 400 mg to be taken as 4 tablets of 100 mg or 1 tablet of 400 mg once a day. 600 mg to be taken as 6 tablets of 100 mg or 1 tablet of 400 mg plus 2 tablets of 100 mg once a day.

For CML, your doctor may prescribe a higher or lower dose depending on how you respond to the treatment. If your daily dose is 800 mg (8 tablets of 100 mg or 2 tablets of 400 mg). You should take 4 tablets of 100 mg or 1 tablet of 400 mg in the morning and 4 tablets of 100 mg or 1 tablet of 400 mg in the evening.

If you are being treated GIST:

The starting dose is 400mg to be taken as 4 tablets of 100mg or as 1 tablet of 400mg once a day. Your doctor may decide to increase the dose to 600 mg, to be taken as 6 tablets of 100mg or as 1 tablet of 400mg plus 2 tablets of 100mg once a day, OR maximum of 800mg, to be taken as 4 tablets of 100mg or 1 tablet of 400mg in the morning and 4 tablets of 100mg or 1 tablet of 400mg in the evening, depending on how you respond to the treatment.

If you are being treated for Ph-positive ALL:

The starting dose is 600 mg to be taken as 6 tablets of 100 mg or one tablet of 400 mg plus 2 tablets of 100 mg once a day.

If you are being treated for MDS/MPD:

The starting dose is 400 mg to be taken as 4 tablets of 100 mg or one tablet of 400 mg once a day.

If you are treated for ASM:

The starting dose is 400mg, to be taken as 4 tablets of 100mg or as 1 tablet of 400mg once a day.

Associated with eosinophilia: The starting dose is 100 mg, to be taken as 1 tablet of 100mg once a day. Your doctor may decide to increase the dose to 400 mg, to be taken as 4 tablets of 100mg or as 1 tablet of 400mg once a day, depending on how you respond to the treatment.

If you are being treated for HES/CEL:

The starting dose is 100 mg, to be taken as one tablet of 100 mg once a day. Your doctor may decide to increase the dose to 400 mg, to be taken as 4 tablets of 100 mg or one tablet of 400 mg once a day, depending on how you respond to treatment.

If you are being treated for DFSP:

The dose is 800 mg per day (to be taken as 4 tablets of 100 mg or 1 tablet of 400 mg in the morning and 4 tablets of 100 mg or 1 tablet of 400 mg in the evening).

Use in children and adolescents

The doctor will tell you how many tablets of Accord Imatinib to give to your child. The amount of Accord Imatinib given will depend on your child's condition, body weight and height. The total daily dose in children and adolescents must not exceed 800 mg with CML and 600 mg with Ph+ALL. The treatment can either be given to your child as a once-daily dose or alternatively the daily dose can be split into two administrations (half in the morning and half in the evening).

- When to use it

Always take Accord Imatinib exactly as when your doctor has told you.

Take Accord Imatinib with a meal. This will help protect you from stomach problems when taking Accord Imatinib.

Swallow the tablets whole with a large glass of water.

- How long to use it

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

- If you forget to take 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 take too much (overdose)

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

While you are using Accord Imatinib

- Things you must do

Your doctor will regularly check whether the medicine is working.

You will also have blood tests and be weighed regularly.

Tell your doctor if you are using medicines that prevent the formation of blood clots.

- Things you must not do

If you are pregnant or breast-

feeding, or think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not breast-feed during the treatment with Accord Imatinib.

- Things to be careful of

Do not give Accord Imatinib to anyone else, even if they have the same condition as you.

You may feel dizzy or drowsy or get blurred vision while taking this medicine. If this happens, do not drive or use any tools or machines until you are feeling well again.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. They are usually mild to moderate. Some side effects may be serious. Tell your doctor straight away if you get any of the following:

Very common:

- Rapid weight gain, fluid retention.
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. Accord Imatinib can reduce the number of white blood cells, so you might get infections more easily.
- Unexpected bleeding or bruising
- Headache or feeling tired.
- Feeling sick (nausea), being sick (vomiting), diarrhoea or indigestion, Rash.
- Muscle cramps or joint, muscle or bone pain, during Accord Imatinib

treatment or after you have stopped taking Accord

Imatinib.

- Swelling such as round your ankles or puffy eyes.
- Weight gain.

Common:

- Anorexia, weight loss or a disturbed sense of taste, Feeling dizzy or weak.
- Difficulty in sleeping (insomnia).
- Discharge from the eye with itching, redness and swelling (conjunctivitis), watery eyes or having blurred vision.
- Nose bleeds, Pain or swelling in your abdomen, flatulence, heartburn or constipation, Itching, Unusual hair loss or thinning, Numbness of the hands or feet
- Mouth ulcers, Joint pain with swelling, Dry mouth, dry skin or dry eye, Decreased or increased skin sensitivity, Hot flushes, chills or night sweats.

Uncommon:

- Chest pain.
- Cough, having difficulty breathing.
- Feeling light-headed, dizzy or fainting.
- Nausea, loss of appetite, dark-coloured urine, yellow skin or eyes.
- Rash, red skin with blisters on the lips, eyes.
- Abdominal pain.
- Severely decreased urine output, feeling thirsty (signs of kidney problems).
- Weakness or paralysis of limbs or face.
- Pale skin, feeling tired and breathlessness.
- Eye pain or deterioration in vision.
- Difficulty hearing.

Rare:

Blood clots in small blood vessels (thrombotic microangiopathy).

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

Storage and disposal of Accord Imatinib

- Storage

Do not store above 30°C.

Keep your medicine in the original pack.

As with all medicines, keep them in safe place out of the reach and sight of children.

Do not use the tablets after the expiry date stated on the carton and blister. The expiry date refers to the last day of that month

- Disposal

If your doctor tells you to stop taking Accord Imatinib or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

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

Imatinib Tablets 100 mg are Brownish orange, round, biconvex, film-coated tablets, debossed with 'IM' and 'T1' on either side of breakline on one side and plain on other side. The breakline is not intended for breaking the tablet.

Imatinib Tablets 400 mg are Brownish orange, oval shaped, biconvex, film-coated tablets, debossed with "IM" and "T2" on either side of breakline on one side and plain on the other side.

The breakline is not intended for breaking the tablet.

- Ingredients

Active ingredient:

Imatinib as Imatinib Mesilate

Inactive Ingredients:

Hypromellose 6 cps Isopropanol

Purified Water Microcrystalline

Cellulose PH 102

Crospovidone

Colloidal Anhydrous Silica

Magnesium Stearate Opadry

Yellow 03F520050

- Nombor MAL:

Imatinib 100 :

MAL20126013AZ

Imatinib 400:

MAL20126014AZ

Manufacturer

Intas Pharmaceuticals Limited

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Product Registration Holder

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Zelan

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