IMATINIB GRINDEKS 100MG HARD CAPSULE

***Imatinib (as Mesylate)* 100mg**

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What Imatinib Grindeks is used for

Imatinib Grindeks is a medicine containing an active substance called imatinib.
Imatinib Grindeks is used in the treatment for adult 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. Imatinib Grindeks inhibits the growth of these cells

Imatinib Grindeks is also used in the treatment for adult for:

- Myelodysplastic/myeloproliferative diseases (MDS/MPD). These are a group of blood diseases in which some blood cells start growing out of control. Imatinib Grindeks 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 Grindeks 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 Grindeks inhibits the growth of these cells
- 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.

In the rest of this leaflet, we will use the abbreviations when talking about these diseases. If you have any questions about how Imatinib Grindeks works or why this medicine has been prescribed for you, ask your doctor.

How Imatinib Grindeks works

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

Before you use Imatinib Grindeks

- *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*

Talk to your doctor before taking Imatinib Grindeks:
- if you have or have ever had a liver, kidney or heart problem.
- if you are taking the medicine levothyroxine because your thyroid has been removed.
- if you have ever had or might now have a hepatitis B infection. This is because Imatinib Grindeks could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.
- if you experience bruising, bleeding, fever, fatigue and confusion when taking Imatinib Grindeks, contact your doctor.This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).

If any of these apply to you, tell your doctor before taking Imatinib Grindeks.

Pregnancy, breast-feeding and fertility
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- Imatinib Grindeks 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 Grindeks during pregnancy.
- Women who might become pregnant are advised to use effective contraception during treatment and for 15 days after ending treatment.
- Do not breast-feed during the treatment with Imatinib Grindeks and for 15 days after ending treatment, as it may harm your baby.
- Patients who are concerned about their fertility while taking Imatinib Grindeks are advised to consult with their doctor.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and including herbal medicines. Some medicines can interfere with the effect of Imatinib Grindeks when taken together. They may increase or decrease the effect of Imatinib Grindeks, either leading to increased side effects or making Imatinib Grindeks less effective. Imatinib Grindeks may do the same to some other medicines.

Some medication will cause complications when taken together with Imatinib Grindeks, such as:
- CYP3A4 inhibitors (e.g. protease

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inhibitors such as indinavir, lopinavir/ritonavir, ritonavir, saquinavir, telaprevir, nelfinavir, boceprevir; azole antifungals including ketoconazole, itraconazole, posaconazole, voriconazole; certain macrolides such as erythromycin, clarithromycin and telithromycin) might cause decreased metabolism and increased imatinib concentration in the body.
- Inducers of CYP3A4 activity (e.g. dexamethasone, phenytoin, carbamazepine, rifampicin, phenobarbital, fosphenytoin, primidone or St. John's Wort) may significantly reduce exposure to Imatinib Grindeks, potentially increasing the risk of Imatinib to lose its efficacy.
-Imatinib Grindeks may increase concentration of other CYP3A4 metabolised drugs (e.g. triazolo-benzodiazepines, dihydropyridine calcium channel blockers, certain HMG-CoA reductase inhibitors, i.e. statins, etc.)
- 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 Imatinib Grindeks
- *How much to use*
- *Use in adults*
Your doctor will tell you exactly how many Capsules of Imatinib Grindeks to take.
- *400 mg* to be taken once a day
- *600 mg* to be taken once a day
- *800 mg* to be taken twice a day

If you are being treated for CML: Depending on your condition the usual dose is either 400 mg or 600 mg and your doctor may decide to increase the dose increased up to 800 mg

If you are being treated for GIST:
The starting dose is 400 mg. Your doctor may decide to increase the dose to 600mg or 800mg

If you are being treated for Ph-positive ALL:
The starting dose is 600 mg.

If you are being treated for MDS/MPD: The starting dose is 400 mg.

If you are being treated for HES/CEL:
The starting dose is 100 mg. Your doctor may decide to increase the dose to 400 mg.

If you are being treated for ASM:
The starting dose is 100 mg. Your doctor may decide to increase the dose to 400 mg.

If you are being treated for DFSP: The dose is 800 mg per day

Use in children and adolescents
The doctor will tell you how many Capsules of Imatinib Grindeks to give to your child. The amount of Imatinib Grindeks given will depend on your child's condition, body weight and height. The total daily dose in children must not exceed 600 mg with Ph+ALL and CML. 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*
- Take Imatinib Grindeks with a meal. This will help protect you from stomach problems when taking Imatinib Grindeks.
- Swallow the Capsules whole with a large glass of water.
If you are unable to swallow the Capsules, you can dissolve them in a glass of still water or apple juice:
□ Use about 50ml for each 100mg Capsule
□ Stir with a spoon until the Capsules have completely dissolved.
□ Once the Capsule has dissolved, drink everything in the glass straight away.

- *How long to use it*
Keep taking Imatinib Grindeks 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 have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- *If you use too much (overdose)*
If you have accidentally taken too many Capsules, talk to your doctor straight away. You may require medical attention. Take the medicine pack with you

While you are using it
- *Things you must do*
- You may become more sensitive to the sun while taking Imatinib Grindeks. It is important to cover sun-exposed areas of skin and use sunscreen with high sun protection factor (SPF). These precautions are also applicable to children.
- During treatment with Imatinib Grindeks, tell your doctor straight away if you put on weight very quickly. Imatinib Grindeks may cause your body to retain water (severe fluid retention).
- While you are taking Imatinib Grindeks, your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

- *Children and adolescents*
Imatinib Grindeks is also a treatment for children with CML. There is no experience in children with CML below 2 years of age. There is limited

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experience in children with Ph-positive ALL and very limited experience in children with MDS/MPD, DFSP, GIST and HES/CEL. Some children and adolescents taking Imatinib Grindeks may have slower than normal growth. The doctor will monitor the growth at regular visits.

- *Things you must not do*
- Do not stop taking your medicines without consulting your doctor.
- Do not use Imatinib Grindeks 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
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 or common:
□ Rapid weight gain. Imatinib Grindeks may cause your body to retain water (severe fluid retention).
□ Signs of infection such as fever, severe chills, sore throat or mouth ulcers. Imatinib Grindeks can reduce the number of white blood cells, so you might get infections more easily.
□ Unexpected bleeding or bruising (when you have not hurt yourself).

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

Other side effects may include:
Very common:
□ Neutropenia (low level of white blood cells), thrombocytopenia (low level of platelet), anaemia (low level of red blood cells)
□ abdominal pain
□ Headache or feeling tired.
□ Feeling sick (nausea), being sick (vomiting), diarrhoea or indigestion.
□ Rash.
□ Muscle cramps or joint, muscle or bone pain, during Imatinib Grindeks treatment or after you have stopped taking Imatinib Grindeks.
□ Swelling such as round your ankles or puffy eyes.
□ Weight gain.
If any of these affects you severely, tell your doctor.

Common:
□ Pancytopenia (low level of red blood cell, white blood cell & platelet)
□ febrile neutropenia (fever in patients with low level of white blood cells)
□ Paresthesia (abnormal sensation of the skin)
□ hypoaesthesia (partial or total loss of sensation in a part of your body)
□ Swellling of the eyelid
□ Hemorrhage (blood loss)
□ Cough
□ Increase in liver enymes level
□ Swelling of the face
□ Anasarca (general swelling of the body)
□ Raised body temperature
□ chills, Rigor
□ 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. If any of these affects you severely, tell your doctor.

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.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Imatinib Grindeks
- *Storage*
Keep out of the reach and sight of children. Store in the original package at temperature not exceeding 30 °C.

- *Disposal*
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description
- *What it looks like*
IMATINIB GRINDEKS 100 MG HARD CAPSULE: Brownish-orange hard gelatine capsules. The content – white to light yellow or brownish yellow powder

- *Ingredients*
- *Active ingredient*
Imatinib (as mesilate) 100mg

- *Inactive ingredients*
Microcrystalline Cellulose, Colloidal Silica Anhydrous, Crospovidone, Talc, Magnesium Stearate and hard gelatin capsule

- *MAL number: MAL22116011AZ*

Manufacturer
JOINT-STOCK COMPANY GRINDEKS.
53, KRUSTPILS STREET, RIGA, LV – 1057, LATVIA.

Product Registration Holder
ABG PHARMA SDN. BHD.
No 26A, Jalan SJ14 Taman Selayang Jaya,

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68100 Batu Caves, Selangor,
Malaysia

Date of revision
18/5/2023

Serial Number
NPRA (R2) 21/168