

GLIVEC® TABLET

Imatinib Mesylate (100mg, 400mg)

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What Glivec is used for

Glivec is a medicine to treat cancer.

Glivec is a treatment for adults and children for:

- chronic myeloid leukemia (CML)
- acute lymphoblastic leukemia (ALL) with Philadelphia chromosome positive (Ph-positive ALL).

Leukemia is cancer of white blood cells. These white blood cells usually help the body to fight infections. CML and ALL are cancers of the blood which makes the body produce too many abnormal white blood cells.

Glivec is also a treatment for adults for:

- Certain types of gastrointestinal stromal tumors (GIST). GIST are cancers of the stomach and the bowels.
- Certain types of dermatofibrosarcoma protuberans (DFSP).

They arise from uncontrolled cell growth.

- Certain types of myelodysplastic/myeloproliferative diseases (MDS/MPD), a group of blood diseases which make the body produce too many abnormal blood cells.
- Certain types of aggressive systemic mastocytosis (ASM).
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL), blood diseases which make the body produce too many blood cells.

How Glivec works

Glivec works by slowing the growth of abnormal cells. Glivec kills the abnormal cells while leaving normal cells alone in the diseases listed above.

If you have any questions about how Glivec works or why this medicine has been prescribed for you, ask your doctor.

Before you use Glivec

Your Glivec treatment will be prescribed by a doctor with experience in the use of anticancer therapies. Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

- When you must not use it
- If you are allergic (hypersensitive) to imatinib or any of the other ingredients of Glivec listed at the end of this leaflet.

If this applies to you, tell your doctor without taking Glivec.

If you think you may be allergic, ask your doctor for advice.

Pregnancy and breast-feeding

Glivec is not recommended during pregnancy unless clearly necessary as it may harm your baby. If you are pregnant or think you may be, tell your doctor, who will discuss with you the potential risk of taking Glivec during pregnancy.

You should not breast-feed while taking Glivec and for 15 days after the last dose, as it may harm your baby. Tell your doctor if you are breast-feeding.

Females of child-bearing potential and male patients

Females of child-bearing potential must use effective birth control while taking Glivec and for 15 days after ending treatment. Male patients concerned about their ability to father children while on Glivec treatment should consult with their physician.

- Before you start to use it
- If any of these applies to you, tell your doctor before taking Glivec:
 - If you have a liver, kidney or heart problem, or used to have one.

- If you are pregnant, or think you may be or if you are breast-feeding (see section Pregnancy and breast-feeding).
- If you are receiving treatment with levothyroxine because your thyroid has been removed.
- If you are receiving treatment with other medicines, in particular medicines listed below in section 'Taking other medicines'.
- If you have ever had or might now have a hepatitis B infection. This is because during treatment with Glivec, hepatitis B may become active again. Your doctor will check for signs of this infection before treatment with Glivec is started.
- if you experience bruising, bleeding, fever, fatigue and confusion when taking Glivec, contact your doctor. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).

Older people (65 years or above)

Glivec can be used by people over the age of 65 at the same dose as other adults.

Children

Some children taking Glivec may have slower than normal growth. The doctor will monitor the growth at regular visits.

Taking other medicines

Glivec may interfere with some other medicines.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- some medicines used to treat infections such as ketoconazole, itraconazole, erythromycin, or clarithromycin,
- some medicines used to treat epilepsy such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, fosphenytoin, or primidone,
- some medicines used to treat high cholesterol such as simvastatin,
- some medicines used to treat mental disorders such as benzodiazepines or pimozide,

- some medicines used to treat high blood pressure or heart disorders such as calcium channel blockers or metoprolol,
- rifampicin, a medicine used to treat tuberculosis,
- St. John's Wort - a herbal product used to treat depression and other conditions (also known as *Hypericum Perforatum*),
- dexamethasone, an anti-inflammatory medicine,
- cyclosporine, an immunosuppressant medicine,
- warfarin, a medicine used to treat blood clot disorders.
- methotrexate, a medicine used to treat cancer, severe rheumatic joint inflammation, or psoriasis.

These medications should be avoided during your treatment with Glivec. If you are taking any of these, your doctor might prescribe other alternative medicines.

You should also tell your doctor if you are already taking Glivec and you are prescribed a new medicine, including medicines obtained without prescription, you have not taken previously during Glivec treatment.

How to use Glivec

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

- How much to use

Adults

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

- **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:

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

- When to use Glivec

Take Glivec with a meal as this will help to protect your stomach. Swallow the tablets whole with a large glass of water.

Method of administration

Film-coated tablets

If you are unable to swallow the tablets, you can stir them into a glass of water or apple juice:

- Put the required tablet(s) in a sufficient quantity of liquid (approximately 50 mL for a 100 mg tablet and 200 mL for a 400 mg tablet).
- Stir with a spoon to completely disintegrate the tablet(s).
- Immediately drink the whole contents of the glass.

- How long to use Glivec

Take Glivec daily until your doctor tells you to stop. Make sure you take Glivec for as long as it is prescribed.

- If you forget to use Glivec

If a dose is missed or vomiting occurs, do not make up the dose. Instead wait until it is time for your next dose.

- If you use too much (overdose)

If you have accidentally taken too many tablets, talk to your doctor immediately. You may require medical attention.

Signs and symptoms of overdosage include: nausea, vomiting, diarrhea, rash, swelling, fatigue, muscle spasms, abdominal pain

While you are using Glivec

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

- Things to be careful of **Driving and using machines**

If you experience symptoms, like dizziness or drowsiness, or if you have blurred vision while taking Glivec, do not drive a vehicle or operate any tools or machines until you are feeling well again.

Monitoring during your treatment with Glivec

Your doctor will regularly monitor your condition to check whether Glivec is having the desired effect. You will also have regular blood tests to see how Glivec is tolerated (e.g. blood cells, liver, thyroid and kidney

function). You will need to have your weight measured regularly.

Side effects

As with all medicines, people treated with Glivec may experience side effects, although not everybody gets them. Most of the side effects are mild to moderate.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Some effects could be serious

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

Very common to common: may affect more than 1 in 10 people

- Rapid weight gain, swelling of extremities (calves, ankles), generalized swelling such as swelling of the face (signs of water retention).
- Weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of low level of blood cells).
- Severe abdominal pain, vomiting blood, finding blood in your stools, or having black stools (signs of gastrointestinal bleeding).
- Nausea, shortness of breath

Uncommon to very rare: may affect up to 1 in every 100 people

- Abnormal laboratory values (such as high potassium, uric acid)
- Pain in bone or joints (signs of osteonecrosis) and inflammation as well as tiredness, loss of appetite, nausea, jaundice (yellowing of the skin), pain in the upper right abdomen, pale stools and dark urine (potential signs of hepatitis B reactivation).
- Irregular heartbeat
- Blood clots in small blood vessels (thrombotic microangiopathy).

Unknown frequency

- Fever, skin rash

Other possible side effects

- Other side effects include the following listed below. If these side effects become severe, please tell your doctor.

- Unable to sleep
- Headache, dizziness, tingling, pain or numbness of the hands, feet, legs or around the hip, taste disturbance, decreased skin sensitivity
- swelling of the eyelids or around the eye, discharge from the eye with redness and itching eye (conjunctivitis), increased tear production, dry eye
- hot flushes
- nose bleeds,
- indigestion, dry mouth, heartburn, swelling in the abdomen, flatulence, constipation
- itchy/red/burning rash, dry skin, unusual hair loss or thinning, night sweats, increased sensitivity of the skin to sun (sign of photosensitivity)
- muscle cramps, fatigue
- musculoskeletal pain after discontinuing treatment with Glivec (including muscle pain, limb pain, joint pain, bone pain and back pain)
- painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin; signs of panniculitis)
- blisters on skin or mucous membranes (signs of pemphigus)

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist or health care provider.

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

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

Storage and disposal of Glivec

- **Storage**
 - Do not use Glivec after the expiry date which is stated on the carton box after EXP. The expiry date refers to the last day of that month
 - Do not use if the pack is damaged or shows signs of tampering.

- Do not store above 30°C and protect from moisture.
- Store in the original package.
- Keep out of the reach and sight of children.

- 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

- Glivec is supplied as very dark yellow to brownish orange film-coated tablets. Each tablet contains 100 mg or 400 mg of the active substance imatinib.
- Glivec 100 mg Tablet - biconvex tablet with imprint “NVR” on one side and “SA” and score on the other side.
- Glivec 400 mg Tablet - ovaloid, biconvex with bevelled edges. Debossed with “400” on one side and score on the other side and “SL” on each side of the score.

- Ingredients

Glivec 100 mg and 400 mg film-coated tablets (divisible)

- Active ingredients

- The active substance of Glivec is imatinib mesylate.

- Inactive ingredients

- The other ingredients are microcrystalline cellulose, crospovidone, hypromellose, magnesium stearate and silica colloidal anhydrous. The coating is composed of hypromellose, macrogol, talc, iron oxide red (E 172) and iron oxide yellow (E 172).

- MAL Number

Glivec 100mg Tablet:
MAL06011679ARZ

Glivec 400mg Tablet:
MAL06011681ARZ

Manufacturer

Novartis Pharma Produktions GmbH
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Product Registration Holder

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