NOVARTIS

GLEEVEC

(imatinib)

100 and 400 mg film-coated tablet

Patient Information Leaflet

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SCHEDULING STATUS S4

GLEEVEC ® FC (film-coated tablet)

GLEEVEC ® 400 (film-coated tablet)

Imatinib

Sugar free

Read all of this leaflet carefully before you start taking GLEEVEC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- GLEEVEC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GLEEVEC is and what it is used for
2. What you need to know before you take GLEEVEC
3. How to take GLEEVEC
4. Possible side effects
5. How to store GLEEVEC
6. Contents of the pack and other information

1. What GLEEVEC is and what it is used for

What GLEEVEC is

GLEEVEC is a medicine to treat cancer. It contains the active substance imatinib.

What GLEEVEC is used for

GLEEVEC is a treatment for adults and children for

- **Chronic myeloid leukaemia (CML)** with Philadelphia chromosome positive (Ph-positive 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 certain abnormal white cells (named myeloid cells) start growing out of control.
- **Acute lymphoblastic leakemia (ALL)** with Philadelphia chromosome positive (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. GLEEVEC inhibits the growth of these cells.

GLEEVEC is also a treatment for adults for

- **Gastrointestinal stromal tumours (GIST).** GIST are cancers of the stomach and the bowels.

They arise from uncotrolled cell growth of the supporting tissue of these organs.

- **Myelodysplastic/myeloproliferative diseases (MDS/MPD).** A group of blood diseases which make the body produce too many abnormal blood cells.
- **Systemic mastocytosis.** Cancers which make the body produce too many blood cells (named “mast” cells)
- **Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL).** Blood diseases which make the body produce too many blood cells (named “eosinophils”).
- **Dermatofibrosarcoma protuberans (DFSP).** DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control.

2. What you need to know before you take GLEEVEC

Your GLEEVEC 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.

Do not take GLEEVEC:

- If you know that you are hypersensitive (allergic) to the active substance or any of the other ingredients of GLEEVEC (listed in section 6).
- If you are pregnant or intend to become pregnant.
- Do not breastfeed your baby if you are taking GLEEVEC.

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

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

Warnings and precautions

Take special care with GLEEVEC

Before taking GLEEVEC, tell your doctor:

- if you have a liver, kidney or heart problem, or have had one of those problems;
- 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 GLEEVEC, hepatitis B may become active again. Your doctor will check for signs of this infection before treatment with GLEEVEC is started.

Check with your doctor if you think any of these may apply to you.

You may become more sensitive to the sun while taking GLEEVEC. 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 GLEEVEC:

If you experience any of the following during your treatment with GLEEVEC, **tell your doctor straight away.** Your doctor might decide to modify or discontinue your treatment.

- 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, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory values (such as high potassium, uric acid, and phosphorous levels and low calcium levels in the blood).

- Fever, skin rash, joint pain 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).

Monitoring during your treatment with GLEEVEC

GLEEVEC may cause your body to retain water (severe fluid retention).

While you are taking GLEEVEC, your doctor will regularly check whether the medicine is working. You will also have blood tests to see how GLEEVEC is tolerated (e.g. blood cells, liver and kidney function). You will be weighed regularly.

GLEEVEC and older people:

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

Children and adolescents (below 18 years)

GLEEVEC is a treatment for children and adolescents with CML. There is no experience with the use of GLEEVEC in children below 2 years of age for CML indication.

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

Other medicines and GLEEVEC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

GLEEVEC may interfere with some other medicines.

Before taking GLEEVEC, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (such as paracetamol) and including herbal medicines (such as St. John’s wort).

These include in particular:

- medicines used to treat infections such as ketoconazole, itraconazole, erythromycin, or clarithromycin,
- some medicines used to treat epilepsy such as carbamazepine, oxcarbazepine, phenobarbitone, phenytoin, fosphenytoin, or primidone,
- some medicines used to treat high cholesterol such as statins,
- 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 coagulation disorders (such as blood clots or thrombosis).

Some medicines can interfere with the effect of GLEEVEC when taken together. They may increase or decrease the effect of GLEEVEC, either leading to increased side effects or making GLEEVEC less effective. GLEEVEC may do the same to some other medicines.

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

Pregnancy, breast-feeding and fertility:

If you are pregnant or intend to become pregnant, or you are breast-feeding your baby, you should not use GLEEVEC, as it may harm your baby. You should also not breast-feed your baby for 15 days after the last dose.

Safety in human pregnancy and lactation has not been established.

Females of child-bearing potential must use effective birth control while taking GLEEVEC and for 15 days after ending treatment.

If you are a man using GLEEVEC, you must use a condom when having sexual intercourse.

Birth defects have occurred in babies when pregnant women were treated with GLEEVEC or whose father used GLEEVEC.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. GLEEVEC may cause dizziness or blurred vision. Therefore, you should wait to know what effects GLEEVEC may cause before driving or using machines. If you feel dizzy or drowsy do not drive, use machines or perform any other tasks that require your attention.

3. How to take GLEEVEC

Do not share medicines prescribed for you with any other person.

Always take GLEEVEC exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Follow all instructions given to you by your doctor carefully.

How much GLEEVEC to take

Use in adults

Your doctor will advise you on how many tablets of GLEEVEC to take

- **If you are being treated for CML**: depending on your condition, the usual starting dose is: either 400 mg to be taken as one tablet of 400 mg once a day, or 600 mg to be taken as one

tablet of 400 mg plus 2 tablets of 100 mg once a day, or 600 mg to be taken as one tablet of 400 mg plus half a 400 mg divisible tablet condition.

- **If you are being treated for GIST:** the starting dose is 400 mg, to be taken as one tablet of 400 mg once a day.
- **If you are being treated for Ph-positive ALL:** the starting dose is 600 mg to be taken as one tablet of 400 mg plus 2 tablets of 100 mg once a day or 600 mg to be taken as one tablet of 400 mg plus half a 400 mg divisible tablet.
- **If you are being treated for MDS/MPD:** the starting dose is 400 mg, to be taken as one tablet of 400 mg once a day.
- **If you are being treated for DFSP:** the starting dose is 800 mg per day, to be taken as one tablet of 400 mg in the morning and a second tablet of 400 mg in the evening.
- **If you are being treated for SM:** the usual starting dose is 400 mg, to be taken as one tablet of 400 mg once a day.

  For some patients (SM associated with eosinophilia), the starting dose is 100 mg once a day to be taken as one tablet of 100 mg.

  Your doctor may decide to increase the dose to 400 mg once a day depending on how you respond to treatment.
- **If you are being treated for HES/CEL:** the usual starting dose is 400 mg, to be taken as one tablet of 400 mg once a day.

  For some patients (HES/CEL with FIP1L1-PDGFR-alpha fusion kinase), the starting dose is 100 mg once a day to be taken as one tablet of 100 mg.

  Your doctor may decide to increase the dose to 400 mg once a day depending on how you respond to treatment.

Children

If your child is being treated for CML or for ALL:

The doctor will tell you how many tablets of GLEEVEC to give your child. The amount of GLEEVEC 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 to be taken as one tablet of 400 mg plus 2 tablets of 100 mg or 600 mg to be taken as one tablet of 400 mg plus half a 400 mg divisible tablet.

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.

When and how to take GLEEVEC

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

For patients unable to swallow the film-coated tablets, the tablets may be dispersed in a glass of water or apple juice. The required number of tablets should be placed in the appropriate volume of liquid and stirred with a spoon.

The suspension should be taken immediately after complete disintegration of the tablet(s).

During the course of the treatment your doctor may adjust the dose to suit your individual needs.

How long to take GLEEVEC:

To benefit from GLEEVEC you must take it every day. Take GLEEVEC daily until your doctor tells you to stop. Make sure you take GLEEVEC for as long as it is prescribed. If you have the impression that the effect of GLEEVEC is too strong or too weak, tell your doctor or pharmacist.

If you take more GLEEVEC than you should

If you accidentally take more GLEEVEC than has been prescribed for you, please consult your doctor immediately. You may require medical attention. In the event of such overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take GLEEVEC

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 have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

GLEEVEC can have side effects.

Not all side effects reported for GLEEVEC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GLEEVEC, please consult your health care provider for advice.

You may tend to see side effects more frequently when you start your medication or increase to a higher dose. In most cases, side effects will gradually disappear as your body becomes used to GLEEVEC.

Side effects are ranked under heading of frequency, the most frequent first, using the following convention: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1 000, < 1/100); rare (≥ 1/10 000, < 1/1 000); very rare (< 1/10 000).

The most frequently reported adverse events are mild nausea, vomiting, diarrhoea, myalgia, muscle cramps and rash, which are easily manageable.

Fluid retention may also occur and can be managed by supportive measures.

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

Very common (may affect more than 1 in 10 people) **to common** (may affect up to 1 in 10 people)

- Rapid weight gain, swelling of extremities (calves, ankles), generalised 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),
- Unexpected bleeding or bruising (when you have not hurt yourself),

Uncommon (may affect up to 1 in 100 people) **to very rare** (may affect up to 1 in 10000)

- Pale skin, tiredness, breathlessness, dark urine (signs of breakdown of red blood cells).
- Vision impairment, blurred vision, blood in eye,
- Crushing chest pain, fever, tiredness, irregular heartbeat (signs of heart disorders such as heart attack, angina),
- Nausea, diarrhoea, vomiting, abdominal pain, fever (signs of inflammatory bowel disease),
- Severe rash, red skin, blistering of the lips, eyes, skin or mouth, skin peeling, fever, red raised or purple skin patches, itching, burning, pustular eruption (signs of skin disorder),
- Pain in bone or joints (signs of osteonecrosis),
- Inflammation of the skin caused by an infection (sign of cellulitis),
- Severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system disorder such as bleeding or swelling in skull / brain),
- Seizure,
- Light-headedness, dizziness or fainting (which may be signs of low blood pressure),
- Severe abdominal pain, vomiting blood, black or bloody stools, or having black stools, swelling of the abdomen/fluid within the abdomen, constipation, stomach pain (signs of gastrointestinal disorders),

- Nausea, loss of appetite, dark-coloured urine or yellowing of your skin or eyes go yellow (sign of liver disorders),
- Thirst, weight loss and severely decreased urine output (signs of low intake of drinks/fluids),
- Blood in urine,
- Swelling and pain in one part of the body (signs of clots in blood vessels),
- Cough, difficult or painful breathing, wheezing, pain in chest when breathing (signs of lung infections/disorders),
- Muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood),
- Muscle spasms, fever, red-brown urine, kidney disorders, pain or weakness in muscles, (signs of muscle disorders),
- Pelvic pain sometimes accompanied by nausea and vomiting, unexpected vaginal bleeding, (signs of gynaecological disorder),
- Severe allergic reaction that can result in difficulty breathing, dizziness (light-headedness),
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory values (such as high potassium, uric acid, and calcium levels and low phosphorous levels in the blood),
- Severe headache, dizziness, blurred vision (signs of increased pressure inside the skull),

Not known (frequency cannot be estimated from the available data):

- Combination of a widespread severe rash, feeling sick, fever, high level of certain white blood cells or yellow skin or eyes (signs of jaundice) with breathlessness, chest pain/discomfort, severely decreased urine output and feeling thirsty (signs of a treatment-related allergic reaction),
- Reactivation of hepatitis B infection when you have had hepatitis B (an infection of the liver) in the past,

Other possible side effects

Tell your doctor if any of the side effects listed below affects you severely.

Very common (may affect more than 1 in 10 people **side effects**

- Headache,
- Nausea,
- Diarrhoea,
- Vomiting,
- Indigestion,
- Abdominal pain,
- Itchy/red/burning rash,
- Muscle cramps,
- Muscle pain,
- Bone pain,
- Joint pain,
- Swelling of the eyelids or around the eye,
- Fatigue,
- Increased weight,
- Musculoskeletal pain after discontinuing treatment with GLEEVEC (including muscle pain, limb pain, joint pain, bone pain and back pain),

Common (may affect up to 1 in 10 people) **side effects**

- Unable to sleep,
- Dizziness,
- Tingling,
- Pain or numbness of the hands, feet, legs or around the hip,

- Taste disturbance,
- Decreased skin sensitivity,
- Discharge from the eye with itching,
- Redness and itching eye (conjunctivitis),
- Increased tear production,
- Dry eye,
- Hot flushes,
- Nose bleeds,
- Dry mouth,
- Heartburn,
- Swelling in the abdomen,
- Flatulence,
- Diarrhoea,
- Constipation,
- Nausea and stomach pain (sign of gastritis),
- Abnormal liver function test results,
- Itching,
- Dry skin,
- Unusual hair loss or thinning,
- Night sweats,
- Increased sensitivity of the skin to sun (sign of photosensitivity),
- Joint swelling,
- Chills,
- Decreased weight,
- Decreased eating,
- Weakness,

- Fever,

Uncommon (may affect up to 1 in 100 people) **side effects**

- Reddening and/or swelling on the palms of the hands and soles of the feet which may be accompanied by tingling sensation and burning pain (also known as hand-foot syndrome),
- Painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin; signs of panniculitis),
- Upper respiratory infection leading to cough, runny or stuffy nose, nasal congestion, sore throat, headache, facial pressure or sneezing,
- severe headache often accompanied by nausea, vomiting and sensitivity to light (signs of migraine),
- Flu-like symptoms,
- Urinary tract infection,
- Swollen/enlarged lymph nodes,
- Painful and swollen joints,
- Depression,
- Anxiety,
- Sleepiness,
- Tremor,
- Memory disorder,
- An urge to move one part of the body (commonly the leg) to stop uncomfortable sensations,
- Eye irritation,
- Eye pain or redness,
- Swelling/itching of the eyelids,
- Spinning sensation/dizziness,
- Difficulty hearing,

- Noises (ringing) in the ears,
- Heart with many extra beats,
- High blood pressure,
- peripheral coldness,
- Belching,
- inflammation of the lips,
- Difficulty swallowing,
- Sweating increased,
- Skin discolouration,
- Brittle nails,
- Breaking of the fingernails or toenails,
- Inflammation of hair follicles,
- Thickened patches of redness around elbows and knees,
- Darkening of skin,
- Breast enlargement in men/women,
- Oedema of the testicles,
- Erection disorder,
- Heavy or irregular menstrual periods,
- Sexual disorder,
- Decreased sexual desire,
- Nipple pain,
- Chest pain,
- Generally feeling unwell,
- Viral infection like cold sore,
- Upper respiratory tract infection that involves the nose air passages (sinusitis), pain in throat,
- Numb or cold toes and fingers (signs of Raynaud’s syndrome),

- Back pain resulting from kidney disorder,
- Increased urinations,
- Increase appetite,
- Ulcer in stomach,
- Joint and muscle stiffness,
- Abnormal laboratory tests results,

Rare side effects (may affect up to 1 in 1,000 people)

- Confusion,
- Nail discolouration,
- Blisters on skin or mucous membranes (signs of pemphigus),

Side effects with frequency not known

- Slowing of growth in children and adolescents,
- Painful and/or blistering skin lesions.

If any of these affects you severely, **tell your doctor.**

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any

possible side effects not listed in this leaflet. You can also report side effects directly to SAHPRA via the Med Safety App (Medsatey X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects you can help provide more information on the safety of GLEEVEC.

5. How to store GLEEVEC

Store all medicines out of the reach and sight of children.

GLEEVEC FC: Store in a cool dry place at or below 30 °C in the original pack.

GLEEVEC 400: Store in a cool dry place at or below 30 °C in the original pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not use after the expiry date stated on the box.

Do not use this medicine if the pack is damaged or shows signs of tampering.

Protect from light / moisture.

The blisters should not be removed from the carton until required for use.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What GLEEVEC contains

GLEEVEC 100 mg and 400 mg film-coated tablets (divisible or non-divisible)

- The active substance of GLEEVEC is imatinib mesilate.
- 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).

What GLEEVEC looks like and contents of the pack

GLEEVEC FC: Very dark yellow to brownish orange, round, biconvex, film-coated tablets with bevelled edges. Debossed with "NVR" on one side and "SA" and a score on the other side.

GLEEVEC 400: Very dark yellow to brownish orange, ovaloid, biconvex, film-coated tablets with bevelled edges. Debossed with "400 on one side and score on the other side and "SL' on each side of the score.

GLEEVEC Tablets are supplied in either 20, 30 or 60 film-coated tablets in colourless, transparent blisters with an aluminium foil backing.

The outer carton is a printed cardboard box.

Holder of Certificate of Registration

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