

Package leaflet: Information for the patient

~~.....~~<Invented name> 100 mg hard capsule
~~.....~~<Invented name> 400 mg hard capsule

Imatinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Formatiert: Einzug: Links: 0 cm, Hängend: 1 cm

1. What ~~.....~~<Invented name> is and what it is used for

Formatiert: Einzug: Links: 0 cm, Hängend: 1 cm

~~.....~~<Invented name> is a medicine containing an active substance called imatinib. This medicine works by inhibiting the growth of abnormal cells in the diseases listed below. These include some types of cancer.

~~.....~~<Invented name> is a treatment for adults 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. ~~.....~~<Invented name> inhibits the growth of these cells.

~~.....~~<Invented name> is also 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. ~~.....~~<Invented name> 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. ~~...../~~<Invented name> 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. ~~...../~~<Invented name> inhibits the growth of these cells.

In the rest of this leaflet, we will use the abbreviations when talking about these diseases.

If you have any questions about how ~~...../~~<Invented name> works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take ~~...../~~<Invented name>

Formatiert: Einzug: Links: 0 cm, Hängend: 1 cm

~~...../~~<Invented name> will only be prescribed to you by a doctor with experience in medicines to treat blood cancers or solid tumours.

Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Do not take ~~...../~~<Invented name>:

- if you are allergic to imatinib or any of the other ingredients of this medicine (listed in section 6).
- If this applies to you, **tell your doctor without taking ~~...../~~<Invented name>.**

If you think you may be allergic but are not sure, ask your doctor for advice.

Warnings and precautions

Talk to your doctor before taking ~~...../~~<Invented name>:

- 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 ~~...../~~<Invented name> 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 any of these apply to you, **tell your doctor before taking ~~...../~~<Invented name>.**

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

While you are taking ~~...../~~<Invented name>, your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

Children and adolescents

~~...../~~<Invented name> is also a treatment for children and adolescents with CML. There is no experience in children with CML below 2 years of age. ~~There is limited experience in children with Ph+ positive ALL below 1 year of age. There is an and with Ph+ ALL below 1 year of age. There is~~ very limited experience in children with MDS/MPD, DFSP, GIST and HES/CEL.

Formatiert: Schriftart: 11 Pt.

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

Other medicines and<Invented name>

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). Some medicines can interfere with the effect of<Invented name> when taken together. They may increase or decrease the effect of<Invented name>, either leading to increased side effects or making<Invented name> less effective.<Invented name> 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 breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

.....<Invented name> 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<Invented name> during pregnancy.

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

Breast-feeding

Do not breast-feed during the treatment with<Invented name>.

Fertility

Patients who are concerned about their fertility while taking<Invented name> are advised to consult with their doctor.

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.

.....<Invented name> contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take<Invented name>

Your doctor has prescribed<Invented name> because you suffer from a serious condition.<Invented name> can help you to fight this condition.

However, always take this medicine exactly as your doctor, or pharmacist or nurse has told you. It is important that you do this as long as your doctor, or pharmacist, or nurse tells you to. Check with your doctor, or pharmacist or nurse if you are not sure.

Formatiert: Einzug: Links: 0 cm, Hängend: 1 cm

Do not stop taking ~~/...../<Invented name>~~ unless your doctor tells you to. If you are not able to take the medicine as your doctor prescribed or you feel you do not need it anymore, contact your doctor straight away.

How much ~~/...../<Invented name>~~ to take

Use in adults

Your doctor will tell you exactly how many capsules of ~~/...../<Invented name>~~ to take.

<100 mg:>

- If you are being treated for CML with “blast crisis”:

Depending on your condition the usual starting dose is either 400 mg or 600 mg:

- **400 mg** to be taken as 4 capsules **once** a day.
- **600 mg** to be taken as 6 capsules **once** a day.

~~The recommended starting dose is 600 mg to be taken as 6 capsules once a day.~~

~~Your doctor may prescribe a higher or lower dose depending on how you respond to treatment. If your daily dose is 800 mg (8 capsules), you should take 4 capsules in the morning and 4 capsules in the evening.~~

- If you are being treated for GIST:

The starting dose is 400 mg, to be taken as 4 capsules **once** a day.

For CML and GIST, 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 capsules), you should take 4 capsules in the morning and 4 capsules in the evening.

- If you are being treated for Ph-positive ALL:

The starting dose is 600 mg to be taken as 6 capsules **once** a day.

- If you are being treated for MDS/MPD:

The starting dose is 400 mg, to be taken as 4 capsules **once** a day.

- If you are being treated for HES/CEL:

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

- If you are being treated for DFSP:

The dose is 800 mg per day (8 capsules), to be taken as 4 capsules in the morning and 4 capsules in the evening.

<400 mg:>

- If you are being treated for CML with “blast crisis”:

Depending on your condition the usual starting dose is either 400 mg or 600 mg:

- **400 mg** to be taken as one capsule **once** a day.
- **600 mg** to be taken as one capsule of 400 mg plus 2 capsules of 100 mg **once** a day.

~~The recommended starting dose is 600 mg to be taken as one capsule of 400 mg, plus 2 capsules of 100~~

Your doctor may prescribe a higher or lower dose depending on how you respond to treatment. If your

- If you are being treated for GIST:

The starting dose is 400 mg, to be taken as one capsule **once** a day.

For **CML and GIST**, your doctor may prescribe a higher or lower dose depending on how you respond to the treatment. If your daily dose is 800 mg (2 capsules), you should take one capsule in the morning and a second capsule in the evening.

- If you are being treated for Ph-positive ALL:

The starting dose is 600 mg to be taken as one capsule of 400 mg plus 2 capsules of 100 mg capsules **once** a day.

- If you are being treated for MDS/MPD:

The starting dose is 400 mg, to be taken as one capsule **once** a day.

- If you are being treated for HES/CEL:

The starting dose is 100 mg, to be taken as one capsule of 100 mg **once** a day. Your doctor may decide to increase the dose to 400 mg, to be taken as one capsule 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 (2 capsules), to be taken as one capsule in the morning and one capsule in the evening.

Use in children and adolescents

The doctor will tell you how many capsules of **<Invented name>** to give to your child. The amount of **<Invented name>** 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 and how to take **<Invented name>**

- **Take **<Invented name>** with a meal.** This will help protect you from stomach problems when taking **<Invented name>**.
- **Swallow the capsules whole with a large glass of water.** Do not open or crush the capsules unless you have difficulty in swallowing (e.g. in children).
- If you are unable to swallow the capsules, you can open them and pour the powder into a glass of still water or apple juice.
- If you are a woman who is pregnant or might get pregnant and are trying to open the capsules, you should handle the contents with caution in order to avoid skin-eye contact or inhalation. You should wash your hands immediately after opening the capsules.

How long to take **<Invented name>**

Keep taking **<Invented name>** every day for as long as your doctor tells you.

If you take more **<Invented name> than you should**

Formatiert: Schriftfarbe: Schwarz, Englisch (Großbritannien)

Formatiert: Einzug: Links: 0,75 cm, Keine Aufzählungen oder Nummerierungen

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.

If you forget to take ~~...../~~<Invented name>

- 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 for a forgotten dose.

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

4. Possible 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 (may affect more than 1 in 10 people) **or common** (may affect up to 1 in 10 people):

- Rapid weight gain. ~~...../~~<Invented name> may cause your body to retain water (severe fluid retention).
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. ~~...../~~<Invented name> 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).

Uncommon (may affect up to 1 in 100 people) **or rare** (may affect up to 1 in 1,000 people):

- Chest pain, irregular heart rhythm (signs of heart problems).
- Cough, having difficulty breathing or painful breathing (signs of lung problems).
- Feeling light-headed, dizzy or fainting (signs of low blood pressure).
- Feeling sick (nausea), with loss of appetite, dark-coloured urine, yellow skin or eyes (signs of liver problems).
- Rash, red skin with blisters on the lips, eyes, skin or mouth, peeling skin, fever, raised red or purple skin patches, itching, burning sensation, pustular eruption (signs of skin problems).
- Severe abdominal pain, blood in your vomit, stools or urine, black stools (signs of gastrointestinal disorders).
- Severely decreased urine output, feeling thirsty (signs of kidney problems).
- Feeling sick (nausea) with diarrhoea and vomiting, abdominal pain or fever (signs of bowel problems).
- Severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system problems, such as bleeding or swelling in skull/brain).
- Pale skin, feeling tired and breathlessness and having dark urine (signs of low levels of red blood cells).
- Eye pain or deterioration in vision, bleeding in the eyes.
- Pain in your hips or difficulty walking.
- Numb or cold toes and fingers (signs of Raynaud's syndrome).
- Sudden swelling and redness of the skin (signs of a skin infection called cellulitis).
- Difficulty hearing.

Formatiert: Einzug: Links: 0 cm, Hängend: 1 cm

- Muscle weakness and spasms with an abnormal heart rhythm (signs of changes in the amount of potassium in your blood).
- Bruising.
- Stomach pain with feeling sick (nausea).
- Muscle spasms with a fever, red-brown urine, pain or weakness in your muscles (signs of muscle problems).
- Pelvic pain sometimes with nausea and vomiting, with unexpected vaginal bleeding, feeling dizzy or fainting due to low blood pressure (signs of problems with your ovaries or womb).
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory test results (e.g. high potassium, uric acid and calcium levels and low phosphorous levels in the blood).

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 etc. (signs of a treatment-related allergic reaction).
- Chronic renal failure.
- [Recurrence \(reactivation\) of hepatitis B infection when you have had hepatitis B in the past \(a liver infection\).](#)

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

Other side effects may include:

Very common (may affect more than 1 in 10 people):

- Headache or feeling tired.
- Feeling sick (nausea), being sick (vomiting), diarrhoea or indigestion.
- Rash.
- Muscle cramps or joint, muscle or bone pain.
- Swelling such as round your ankles or puffy eyes.
- Weight gain.

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

Common (may affect up to 1 in 10 people):

- 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**.

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

- 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.
- Slowing of growth in children and adolescents.

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

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 via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ~~/...../~~<Invented name>

Store below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of the month.

Do not use any pack that is damaged or shows signs of tampering.

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.

6. Contents of the pack and other information

What ~~/...../~~<Invented name> contains

<100 mg:>

- The active substance is imatinib mesilate. Each capsule of ~~/...../~~<Invented name> contains 100 mg of imatinib (as mesilate).

<400 mg:>

- The active substance is imatinib mesilate. Each capsule of ~~/...../~~<Invented name> contains 400 mg of imatinib (as mesilate).

<100 mg:>

- The other ingredients are crospovidone (type A), lactose monohydrate and magnesium stearate
- The capsule shell is made of gelatine, yellow iron oxide (E172), titanium dioxide (E171) and red iron oxide (E172).

<400 mg:>

- The other ingredients are crospovidone (type A), lactose monohydrate and magnesium stearate
- The capsule shell is made of gelatine, yellow iron oxide (E172), titanium dioxide (E171), red iron oxide (E172) and black iron oxide (E172).

Formatiert: Einzug: Links: 0 cm, Hängend: 1 cm

Formatiert: Einzug: Links: 0 cm, Hängend: 1 cm

What ~~/...../~~<Invented name> looks like and contents of the pack

<100 mg:>

~~/...../~~<Invented name> 100 mg hard capsules are gelatin capsules of size “3” with orange body and cap. They are supplied in packs containing 30, 60, 100, 120 or 180 capsules, but these may not all be available in your country.

<400 mg:>

~~/...../~~<Invented name> 400 mg hard capsule are gelatin capsules of size “00” with caramel body and cap. They are supplied in packs containing 10, 30, 90 or 100 capsules, but these may not all be available in your country.

Marketing Authorisation Holder

(To be completed nationally).

Manufacturer

(To be completed nationally).

<For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.>

This medicinal product is authorised in the Member States of the EEA under the following names:

{Name of the Member State} {Name of the medicinal product}

This leaflet was last revised in October 2016

Formatiert: Leerraum zwischen asiatischem und westlichem Text nicht anpassen, Leerraum zwischen asiatischem Text und Zahlen nicht anpassen

Formatiert: Leerraum zwischen asiatischem und westlichem Text nicht anpassen, Leerraum zwischen asiatischem Text und Zahlen nicht anpassen