Bijsluiter: informatie voor de patiënt

Imatinib Sandoz® 100 mg, filmomhulde tabletten
Imatinib Sandoz® 400 mg, filmomhulde tabletten

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 [Nationally completed name] is and what it is used for

[Nationally completed 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.

[Nationally completed 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. [Nationally completed name] inhibits the growth of these cells.

[Nationally completed 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. [Nationally completed 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. [Nationally completed 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. [Nationally completed 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 [Nationally completed name] works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take [Nationally completed name]

[Nationally completed 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 [Nationally completed 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 [Nationally completed 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 [Nationally completed 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 [Nationally completed 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 you experience bruising, bleeding, fever, fatigue and confusion when taking [product], 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 [Nationally completed name].**

You may become more sensitive to the sun while taking [Nationally completed name]. 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 [Nationally completed name], tell your doctor straight away if you put on weight very quickly. [Nationally completed name] may cause your body to retain water (severe fluid retention).

While you are taking [Nationally completed name], your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

Children and adolescents
[Nationally completed name] is also a treatment for children 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 and very limited experience in children with MDS/MPD, DFSP, GIST and HES/CEL.

Some children and adolescents taking [Nationally completed name] may have slower than normal growth. The doctor will monitor the growth at regular visits.

Other medicines and [Nationally completed 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 [Nationally completed name] when taken together. They may increase or decrease the effect of [Nationally completed name], either leading to increased side effects or making [Nationally completed name] less effective. [Nationally completed 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.
- [Nationally completed 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 [Nationally completed name] 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 [Nationally completed name] and for 15 days after ending treatment, as it may harm your baby.
- Patients who are concerned about their fertility while taking [Nationally completed 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.

3. How to take [Nationally completed name]

Your doctor has prescribed [Nationally completed name] because you suffer from a serious condition. [Nationally completed name] can help you to fight this condition.

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

Do not stop taking [Nationally completed 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 [Nationally completed name] to take

Use in adults
Your doctor will tell you exactly how many tablets of [Nationally completed name] 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 **once** a day,
  - 600 mg to be taken as 6 tablets **once** a day.
  - 400 mg to be taken as one tablet **once** a day.
  - 600 mg to be taken as one tablet of 400 mg plus half a tablet of 400 mg (or 2 tablets of 100 mg) **once** a day.

- **If you are being treated for GIST:**
  The starting dose is 400 mg, to be taken as 4 tablets **once** a day.
  The starting dose is 400 mg, to be taken as one tablet **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 tablets), you should take 4 tablets in the morning and 4 tablets in the evening. If your daily dose is 800 mg (2 tablets), you should take one tablet in the morning and one tablet in the evening.

- **If you are being treated for Ph-positive ALL:**
  The starting dose is 600 mg to be taken as 6 tablets **once** a day.
  The starting dose is 600 mg to be taken as one tablet of 400 mg plus half a tablet of 400 mg (or 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 **once** a day.

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

- **If you are being treated for HES/CEL:**
  The starting dose is 100 mg, to be taken as one tablet **once** a day. Your doctor may decide to increase the dose to 400 mg, to be taken as 4 tablets **once** a day, depending on how you respond to treatment.
  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 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 (8 tablets), to be taken as 4 tablets in the morning and 4 tablets in the evening.
  The dose is 800 mg per day (2 tablets), to be taken as one tablet in the morning and one tablet in the evening.

Use in children and adolescents
The doctor will tell you how many tablets of [Nationally completed name] to give to your child. The amount of [Nationally completed name] given will depend on your child's condition, body weight and height. The total daily dose in children 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).

The film-coated tablet can be divided into equal doses.

When and how to take [Nationally completed name]
- Take [Nationally completed name] with a meal. This will help protect you from stomach problems when taking [Nationally completed name].
- Swallow the tablets whole with a large glass of water.

If you are unable to swallow the tablets, you can dissolve them in a glass of still water or apple juice:
- Use about 50 ml for each 100 mg tablet.
  Use about 200 ml for each 400 mg tablet or about 100 ml for half a 400 mg tablet.
- Stir with a spoon until the tablets have completely dissolved.
- Once the tablet has dissolved, drink everything in the glass straight away. Traces of the dissolved tablets may be left behind in the glass.

How long to take [Nationally completed name]
Keep taking [Nationally completed name] every day for as long as your doctor tells you.

If you take more [Nationally completed name] than you should
If you have accidentally taken too many tablets, talk to your doctor **straight away**. You may require medical attention. Take the medicine pack with you.

If you forget to take [Nationally completed 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 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. [Nationally completed name] may cause your body to retain water (severe fluid retention).
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. [Nationally completed 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).
- Painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin).
- 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.
- 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 (eg. high potassium, uric acid and calcium levels and low phosphorous levels in the blood).
- Blood clots in small blood vessels (thrombotic microangiopathy)

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, during [Nationally completed name] treatment or after you have stopped taking [Nationally completed name].
- 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.
- Painful and/or blistering skin lesions.
- 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 [Nationally completed name]

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 blister and carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

PVC/PE/PVDC/aluminium blisters [NL/H/3318-3319/002]
Store below 25°C

Store in the original package in order to protect from moisture.

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 [Nationally completed name] contains
- The active substance is imatinib mesilate.
Each film-coated tablet contains 100 mg of imatinib (as mesilate).
Each film-coated tablet contains 400 mg of imatinib (as mesilate).

- The other ingredients of tablet core are microcrystalline cellulose, crospovidone (type A), hypromellose, magnesium stearate, colloidal anhydrous silica.
- The other ingredients of tablet coating are red iron oxide (E 172), yellow iron oxide (E 172), macrogol 4000, talc, hypromellose.

What [nationally completed name] looks like and contents of the pack

Each [Nationally completed name] film-coated tablet, with an approximate diameter of 9.2 mm, is very dark yellow to brownish orange, round, biconvex with bevelled edges, debossed with “NVR” on one side and “SA” and score between the letters on the other side.
Each [Nationally completed name] film-coated tablet, with an approximate length of 19.2 mm and width of 7.7 mm, is very dark yellow to brownish orange, 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.

[NL/H/3318/001]
The tablets are packed in PVC/aluminium or PVC/PE/PVDC/aluminium blisters and inserted in a carton, with pack sizes of 20, 30, 50, 60, 80, 90 or 120 film-coated tablets.
[NL/H/3319/001]
The tablets are packed in PVC/aluminium or PVC/PE/PVDC/aluminium blisters and inserted in a carton, with pack sizes of 60 or 120 film-coated tablets.

[NL/H/3318/002]
The tablets are packed in PVC/PE/PVDC/aluminium blisters and inserted in a carton, with pack sizes of 10, 30, 50, 60, 80 or 90 film-coated tablets.
[NL/H/3319/002]
The tablets are packed in PVC/PE/PVDC/aluminium blisters and inserted in a carton, with pack sizes of 10, 30 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikant:
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

Novartis Pharma GmbH

Roonstrasse 25
D-90429 Nuremberg
Duitsland

Lek Pharmaceuticals d.d.
Trimlini 2D
9220 Lendava
Slovenië

In het register ingeschreven onder:
Imatinib Sandoz 100 mg is in het register ingeschreven onder RVG 116276.
Imatinib Sandoz 400 mg is in het register ingeschreven onder RVG 116277.

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland:	Imatinib Sandoz 100 mg, 400 mg, filmomhulde tabletten
Oostenrijk:	Imatinib 1A Pharma 100 mg, 400 mg – Filmtabletten
Duitsland:	Imatinib 1A Pharma 100 mg, 400 mg Filmtabletten
Malta:	Imatinib 1A Pharma 100 mg, 400 mg Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2022