

Package leaflet: Information for the user

Imatinib Clonmel 100mg Film-coated Tablets Imatinib Clonmel 400mg Film-coated Tablets

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

1. What Imatinib Clonmel is and what it is used for

Imatinib Clonmel 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.

Imatinib Clonmel 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. Imatinib Clonmel inhibits the growth of these cells.

Imatinib Clonmel 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. Imatinib Clonmel 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 Clonmel inhibits the growth of these cells in a certain subtype of these diseases.
- **Dermatofibrosarcoma protuberans (DFSP).** DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control. Imatinib Clonmel 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 Imatinib Clonmel works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Imatinib Clonmel

Imatinib Clonmel 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 Imatinib Clonmel

- 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 Imatinib Clonmel.**

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 Imatinib Clonmel:

- 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 Clonmel 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 Imatinib Clonmel.

During treatment with Imatinib Clonmel, tell your doctor straight away if you put on weight very quickly. Imatinib Clonmel may cause your body to retain water (severe fluid retention).

While you are taking Imatinib Clonmel, your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

Children and adolescents

Imatinib Clonmel 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 and HES/CEL.

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

Other medicines and Imatinib Clonmel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can interfere with the effect of Imatinib Clonmel when taken together. They may increase or decrease the effect of Imatinib Clonmel either leading to increased side effects or making Imatinib Clonmel less effective. Imatinib Clonmel 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.
- Imatinib Clonmel 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 Clonmel during pregnancy.
- Women who might become pregnant are advised to use effective contraception during treatment.
- Do not breast-feed during the treatment with Imatinib Clonmel.

- Patients who are concerned about their fertility while taking Imatinib Clonmel 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 Imatinib Clonmel

Your doctor has prescribed Imatinib Clonmel because you suffer from a serious condition. Imatinib Clonmel can help you to fight this condition.

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.

After each administration of film-coated tablets, please reinsert purified rayon into the bottle to prevent film-coated tablets from physical damage.

How much Imatinib Clonmel to take

Use in adults:

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

- If you are being treated for CML:

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

- **400 mg** to be taken as 4 tablets of 100 mg once a day.
- **600 mg** to be taken as 6 tablets of 100 mg once a day.
- **400 mg** to be taken as 1 tablet of 400 mg once a day.
- **600 mg** to be taken as 1 tablet of 400 mg plus 2 tablets of 100 mg once a day.

For CML, 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 of 100 mg), you should take 4 tablets of 100 mg in the morning and 4 tablets of 100 mg in the evening.

For CML, 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 tablets of 400 mg), you should take 1 tablet of 400 mg in the morning and a second tablet of 400 mg in the evening.

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

The starting dose is 600 mg, to be taken as:

- 6 tablets of 100 mg once a day.
- 1 tablet of 400 mg plus 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 of 100 mg once a day.
- 1 tablet of 400 mg once a day.

- If you are being treated for HES/CEL:

The starting dose is 100 mg, to be taken as 1 tablet of 100 mg once a day. Your doctor may decide to increase the dose to 400 mg, to be taken as:

- 4 tablets of 100 mg once a day, depending on how you respond to the treatment.
- 1 tablet of 400 mg once a day, depending on how you respond to the treatment.

- If you are being treated for DFSP:

The dose is 800 mg per day, to be taken as:

- 4 tablets of 100 mg in the morning and 4 tablets of 100 mg in the evening.
- 1 tablet of 400 mg in the morning and a second tablet of 400 mg in the evening.

Use in children and adolescents

The doctor will tell you how many tablets of Imatinib Clonmel to give to your child. The amount of Imatinib Clonmel 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).

When and how to take Imatinib Clonmel

- **Take Imatinib Clonmel with a meal.** This will help protect you from stomach problems when taking Imatinib Clonmel.
- **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
- 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 Imatinib Clonmel

Keep taking Imatinib Clonmel every day for as long as your doctor tells you.

If you take more Imatinib Clonmel 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 Imatinib Clonmel

- 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 stop taking Imatinib Clonmel

Do not stop taking Imatinib Clonmel 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.

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. Imatinib Clonmel may cause your body to retain water (severe fluid retention).
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. Imatinib Clonmel 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.
- 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, during Imatinib Clonmel treatment or after you have stopped taking Imatinib Clonmel.
- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Imatinib Clonmel

- 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, blister or bottle after EXP. The expiry date refers to the last day of that month.

HDPE bottle: After first opening

Imatinib Clonmel 100 mg 60 film-coated tablets/bottle 180 days

Imatinib Clonmel 100 mg 90 film-coated tablets/bottle 135 days

Imatinib Clonmel 400 mg 30 film-coated tablets/bottle 45 days

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

6. Contents of the pack and other information

What Imatinib Clonmel contains

The active substance is imatinib mesilate.

Each film-coated tablet contains 100 mg imatinib (as mesilate).

Each film-coated tablet contains 400 mg imatinib (as mesilate).

The other ingredients are:
Sodium stearyl fumarate.

The tablet coating is made of:
Opadry Brown consisting of hypromellose, red iron oxide (E172), yellow iron oxide (E172), talc.

What Imatinib Clonmel looks like and contents of the pack

Imatinib Clonmel 100 mg film-coated tablets are brownish, round, biconvex, film-coated tablets debossed with “100” on one side and a score line on the other side, with “N” on one side of the score line and “I” on the other side of the score line.

Thickness: approx. 2.9 – 3.5 mm

Diameter: approx. 6.9 – 7.3 mm

The tablet can be divided into equal halves.

Imatinib Clonmel 400 mg film-coated tablets are brownish, oval, biconvex, film-coated tablets debossed with “400” on one side and “NI” on the other side.

Thickness: approx. 5.0 – 5.7 mm

Length: approx. 16.9 – 17.3 mm

Imatinib Clonmel film-coated tablets are supplied in alu/alu blister or HDPE bottle with child resistant PP/PE closure including purified rayon inside.

Imatinib Clonmel 100 mg:

alu/alu blister: 10, 30, 50 (clinical pack), 60, 90, 100, 120, 150, 180 and 200

HDPE bottle with child resistant PP/PE closure including purified rayon: 1x60 tablets, 1x 90, 120 (2x 60 tablets), 180 (3x60 tablets)

Imatinib Clonmel 400 mg:

alu/alu blister :10, 30, 50 (clinical pack), 60, 90, 100, 120, 150, 180 and 200

HDPE bottle with child resistant PP/PE closure including purified rayon: 1x30 tablets, 90 (3x30 tablets)

Not all pack sizes may be available in your country.

Marketing authorisation holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

S.C. POLISANO PHARMACEUTICALS, S.A., Alba Iulia Street, No. 156, 550052 Sibiu, Romania

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

STADAPHARM GmbH, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

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

Germany:	Imatinib AL 100 mg and 400 mg Filmtabletten
Belgium:	Imatinib EG 100 mg and 400 mg filmomhulde tabletten
Czech Republic:	IMATINIB STADA 100 mg and 400 mg potahované tablety
Denmark:	Imatinib STADA
Finland:	Imatinib STADA
France:	Imatinib EG 100 mg and 400 mg, comprimé pelliculé
Hungary:	Imatinib Stada 100 mg and 400 mg filmtableta
Ireland:	Imatinib Clonmel 100 mg and 400 mg film-coated tablets
Luxembourg:	Imatinib EG 100 mg and 400 mg comprimés pelliculés
The Netherlands:	Imatinib CF 100 mg and 400 mg, filmomhulde tabletten
Romania:	Imatinib STADA 100 mg comprimate filmate
Sweden:	Imatinib STADA

Slovenia: Imatinib STADA 100 mg and 400 mg filmsko obložene tablete
Slovakia: Imatinib STADA 100 mg and 400 mg filmom obalené tablety

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