Package leaflet: Information for the patient

Imatinib Rowex 100 mg film-coated tablets
Imatinib Rowex 400 mg 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 Rowex is and what it is used for
2. What you need to know before you take Imatinib Rowex
3. How to take Imatinib Rowex
4. Possible side effects
5. How to store Imatinib Rowex
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1. What Imatinib Rowex is and what it is used for

Imatinib Rowex 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 Rowex 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 Rowex inhibits the growth of these cells.

Imatinib Rowex 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 Rowex 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 Rowex 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. Imatinib Rowex 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 Rowex works or why this medicine has been prescribed for you, ask your doctor.

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

Imatinib Rowex 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 Rowex
- 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 Rowex.**

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 Rowex:
- 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 Rowex 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 Imatinib Rowex, 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 Imatinib Rowex.**

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

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

Children and adolescents
Imatinib Rowex 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 Imatinib Rowex may have slower than normal growth. The doctor will monitor the growth at regular visits.

Other medicines and Imatinib Rowex

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

Your doctor has prescribed Imatinib Rowex because you suffer from a serious condition. Imatinib Rowex 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 Imatinib Rowex 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 Imatinib Rowex to take
Use in adults
Your doctor will tell you exactly how many tablets of Imatinib Rowex to take.

- **If you are being treated for CML:**
  Depending on your condition the usual starting dose is either **400 mg** or **600 mg** to be taken **once** a day.

- **If you are being treated for GIST:**
  The starting dose is 400 mg, to be taken **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, you should take 400 mg in the morning and 400 mg in the evening.

- **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 HES/CEL:**
  The starting dose is 100 mg, to be taken **once** a day. Your doctor may decide to increase the dose to 400 mg, to be taken **once** a day, depending on how you respond to treatment.

- **If you are being treated for DFSP:**
  The dose is 800 mg per day, to be taken as 400 mg in the morning and 400 mg in the evening.

A 400 mg dose can be taken either as 1 tablet of 400 mg or 4 tablets of 100 mg.
A 600 mg dose can be taken either as 1 tablet of 400 mg plus 2 tablets of 100 mg or as 1 tablet of 400 mg plus half of 1 tablet of 400 mg.

The tablets can be divided in half by breaking along the score line.

Use in children and adolescents
The doctor will tell you how many tablets of Imatinib Rowex to give to your child. The amount of Imatinib Rowex 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 Rowex
- **Take Imatinib Rowex with a meal.** This will help protect you from stomach problems when taking Imatinib Rowex.
- **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 or 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 Rowex
Keep taking Imatinib Rowex every day for as long as your doctor tells you.

If you take more Imatinib Rowex 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 Rowex
- 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. Imatinib Rowex may cause your body to retain water (severe fluid retention).
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. Imatinib Rowex 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 bones or joints (signs of osteonecrosis).
- Blisters on skin or mucous membranes (signs of pemphigus).
- 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).
- 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 Imatinib Rowex treatment or after you have stopped taking Imatinib Rowex.
- 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**.

Uncommon (may affect up to 1 in 100 people):
- Painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin).
- Cough, runny or stuffy nose, feeling of heaviness or pain on pressing the area above the eyes or on the sides of the nose, nasal congestion, sneezing, sore throat, with or without headache (signs of upper respiratory tract infection).
- Severe headache felt as a throbbing pain or pulsing sensation, usually on one side of the head and often accompanied by nausea, vomiting and sensitivity to light or sound (signs of migraine).
- Flu-like symptoms (influenza).

- Pain or burning sensation while passing urine, increased body temperature, pain in groin or pelvic area, red- or brown-coloured or cloudy urine (signs of urinary tract infection).
- Pain and swelling of your joints (signs of arthralgia).
- A constant feeling of sadness and loss of interest, which stops you carrying out your normal activities (signs of depression).
- A feeling of apprehension and worry along with physical symptoms such as pounding heart, sweating, trembling, dry mouth (signs of anxiety).
- Sleepiness/drowsiness/excessive sleep.
- Trembling or shaky movements (tremor).
- Memory impairment.
- Overwhelming urge to move the legs (restless leg syndrome).
- Hearing noises (e.g. ringing, humming) in the ears that have no external source (tinnitus).
- High blood pressure (hypertension).
- Burping/belching.
- Inflammation of the lips.
- Difficulty swallowing.
- Increased sweating.
- Skin discolouration.
- Brittle nails.
- Red bumps or white-headed pimples around the roots of the hair, possibly with pain, itching or burning sensation (signs of inflammation of the hair follicles, also called folliculitis).
- Skin rash with flaking or peeling (exfoliative dermatitis).
- Breast enlargement (may occur in men or women).
- Dull pain and/or feeling of heaviness in the testicles or lower abdomen, pain during urination, sexual intercourse or ejaculation, blood in urine (signs of oedema of the testicles).
- Inability to get or keep an erection (erectile dysfunction).
- Heavy or irregular menstrual periods.
- Difficulty achieving/maintaining sexual arousal.
- Decreased sexual desire.
- Nipple pain.
- Generally feeling unwell (malaise).
- Viral infection such as cold sore.
- Lower back pain resulting from kidney disorder.
- Increased frequency of passing urine.
- Increase in appetite.
- Pain or burning sensation in upper abdomen and/or chest (heartburn), nausea, vomiting, acid reflux, feeling of fullness and bloating, black-coloured stools (signs of stomach ulcer).
- Joint and muscle stiffness.
- Abnormal laboratory test results.

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

Rare (may affect up to 1 in 1 000 people):
- Confusion.
- An episode of spasm(s) and reduced consciousness (convulsions).
- Nail discolouration.

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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Imatinib Rowex

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 that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice it 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 Imatinib Rowex contains
- The active substance is imatinib mesilate.
- Each film-coated tablet of Imatinib Rowex contains imatinib mesilate equivalent to 100 mg imatinib.
- Each film-coated tablet of Imatinib Rowex contains imatinib mesilate equivalent to 400 mg imatinib.
- The other ingredients are: tablet core: magnesium stearate. The tablet coating is made of Hypromellose 2910, titanium dioxide (E171), macrogol 8000 (E1521), talc (E553b).

What Imatinib Rowex looks like and contents of the pack
Imatinib Rowex 100 mg film-coated tablets (tablet)
White to off-white coloured, round, bevel edged scored, film-coated tablets debossed with **H** on one side and **19** on the other side, **1** and **9** separated by a score line, with diameter of 7.05-7.25 mm and a thickness of 3.0-3.6 mm.

This product is available with pack size of:
Alu/PVC-Alu-OPA blister: 30, 60, 90, and 120 film-coated tablets.
Alu/PVC-Alu-OPA unit dose blister: 30 × 1, 60 × 1, 90 × 1, and 120 × 1 film-coated tablets.

Imatinib Rowex 400 mg film-coated tablets (tablet)
White to off-white coloured, capsule shaped, bevel edged scored, film-coated tablets debossed with **H** on one side and **20** on the other side, **2** and **0** separated by a score line, with length of 14.90-15.10 mm, width of 6.40-6.60 mm and thickness of 5.2-6.0 mm.

This product is available with pack size of:
Alu/PVC-Alu-OPA blister: 30, 60, 90, film-coated tablets.
Alu/PVC-Alu-OPA unit dose blister: 30 × 1, 60 × 1, and 90 × 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Pharmadox Healthcare Limited, KW20A Kordin Industrial Park, PLA 3000 Paola, Malta.
Salutas Pharma GmbH., Otto-Von-Guericke-Allee 1, 39179 Barleben, Saxony-Anhalt, Germany.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Imatinib Sandoz GmbH
Czechia	Imatinib Sandoz GmbH
Germany	Imatinib HEXAL
Denmark	Imatinib Hexal
Spain	Imatinib Sandoz Farmacéutica
Finland	Imatinib Hexal
France	IMATINIB GNR
Ireland	Imatinib Rowex
Italy	Imatinib Sandoz GmbH
Netherlands	Imatinib Sandoz
Poland	Imatinib Sandoz
Sweden	Imatinib Hexal
Slovakia	Imatinib Sandoz GmbH

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