

## Package leaflet: Information for the patient

### Imatinib Teva Pharma 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

#### **What is in this leaflet:**

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

#### **1. What Imatinib Teva Pharma is and what it is used for**

Imatinib Teva Pharma is a medicine containing an active substance called imatinib. This medicine works by inhibiting the growth of abnormal cells in **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.

In adult patients Imatinib Teva Pharma is used to treat a late stage of Chronic Myeloid Leukaemia called “blast crisis.” In children however it may be used to treat all stages of the illness.

In the rest of this leaflet, we will use the abbreviation, CML, when talking about this disease.

If you have any questions about how Imatinib Teva Pharma works or why this medicine has been prescribed for you, ask your doctor.

#### **2. What you need to know before you take Imatinib Teva Pharma**

Imatinib Teva Pharma will only be prescribed to you by a doctor with experience in medicines to treat blood cancers.

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

#### **Do not take Imatinib Teva Pharma**

- 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 Teva Pharma .**

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

#### **Warning and precautions**

Talk to your doctor before taking Imatinib Teva Pharma :

- 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 any of these apply to you, **tell your doctor before taking Imatinib Teva Pharma**

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

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

### **Children and adolescents**

Imatinib Teva Pharma is also a treatment for children with CML. There is no experience in children with CML below 2 years of age.

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

### **Other medicines and Imatinib Teva Pharma**

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 Teva Pharma when taken together. They may increase or decrease the effect of Imatinib Teva Pharma, either leading to increased side effects or making Imatinib Teva Pharma less effective. Imatinib Teva Pharma 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 Teva Pharma 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 Teva Pharma during pregnancy.
- Women who might become pregnant are advised to use effective contraception during treatment.
- Do not breast-feed during the treatment with Imatinib Teva Pharma .
- Patients who are concerned about their fertility while taking Imatinib Teva Pharma 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 Teva Pharma**

Your doctor has prescribed Imatinib Teva Pharma because you suffer from a serious condition. Imatinib Teva Pharma 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 Teva Pharma 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 Teva Pharma to take**

### **Use in adults**

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

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

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), you should take one tablet in the morning and a second tablet in the evening.

### **Use in children and adolescents**

The doctor will tell you how many tablets of Imatinib Teva Pharma to give to your child. The amount of Imatinib Teva Pharma given will depend on your child's condition, body weight and height. The total daily dose in children must not exceed 800 mg. 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 tablet can be divided into equal doses by breaking it through the score line in case your doctor has prescribed you or your child a dose where half of a tablet is needed.

### **When and how to take Imatinib Teva Pharma**

- **Take Imatinib Teva Pharma with a meal.** This will help protect you from stomach problems when taking Imatinib Teva Pharma.
- **Swallow the tablets 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 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 Teva Pharma**

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

### **If you take more Imatinib Teva Pharma 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 Teva Pharma**

- 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.

These side effects may occur with certain frequencies, which are defined as follows:

- Very common: may affect more than 1 in 10 people.
- Common: may affect up to 1 in 10 people.
- Uncommon: may affect up to 1 in 100 people.
- Rare: may affect up to 1 in 1,000 people.
- Very rare: may affect up to 1 in 10,000 people.
- Not known: frequency cannot be estimated from the available data.

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

**Very common or common side effects:**

- Rapid weight gain. Imatinib Teva Pharma may cause your body to retain water (severe fluid retention).
- Signs of infection such as fever, severe chills, sore throat or mouth ulcers. Imatinib Teva Pharma 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 or rare side effects:**

- 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, light-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.
- 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 cellulites).
- 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 phosphorous levels and low calcium levels in the blood).

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

**Other side effects may include:**

**Very common side effects:**

- 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 side effects:**

- 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:**

- 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Imatinib Teva Pharma**

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.

This medicine does not require any special storage conditions.

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 Imatinib Teva Pharma contains**

- The active substance is imatinib mesilate. Each tablet of Imatinib Teva Pharma contains 400 mg imatinib (as mesilate).
- The other ingredients are mannitol, crospovidone, sodium starch glycolate type A, magnesium stearate and silica, colloidal anhydrous.
- The tablet coating is made of macrogol poly(vinyl alcohol) grafted copolymer, poly(vinyl alcohol), silica, talc, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

### **What Imatinib Teva Pharma looks like and contents of the pack**

Imatinib Teva Pharma 400 mg film-coated tablets are orange-brown, oblong, film-coated tablets debossed with 7630 on one side and a score line on the other side. The tablet is debossed with 9 and 3 at each side of the score line.

The film-coated tablets have dimensions of 20.5 mm x 10 mm.

Imatinib Teva Pharma is available in packs of 30 or 90 film-coated tablets in blisters.

Imatinib Teva Pharma is available in packs of 30x1 or 90x1 film-coated tablets in perforated unit dose blisters

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder:

Teva Pharma B.V.  
Computerweg  
3542 DR Utrecht  
The Netherlands

#### Manufacturer:

Teva Operations Poland Sp. z.o.o.  
Ul. Mogilska 80.  
31-546, Krakow  
Poland

Teva Pharmaceutical Works Private Limited Company,  
Pallagi út 13  
4042 Debrecen  
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East Sussex  
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Swensweg 5,  
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The Netherlands

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)  
Address: Prilaz baruna Filipovića 25,  
10000  
Zagreb  
Croatia

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

Austria	Imatinib ratiopharm
Belgium	Imatinib ratiopharm
Bulgaria	Imatinib Teva Pharma
Cyprus	Imatinib Teva Pharma
Czech Republic	Imatinib Teva Pharma
Denmark	Imatinib Teva Pharma
Estonia	Imatinib Teva Pharma
Finland	Imatinib ratiopharm
France	Imatinib ratiopharm
Germany	Imatinib ratiopharm
Greece	Imatinib Teva Pharma
Hungary	Imatinib ratiopharm
Iceland	Imatinib ratiopharm
Ireland	Imatinib Teva Pharma
Italy	Imatinib Teva Italia
Latvia	Imatinib Teva Pharma
Lithuania	Imatinib Teva Pharma
Luxembourg	Imatinib ratiopharm
Malta	Imatinib Teva Pharma
Netherlands	Imatinib ratiopharm
Norway	Imatinib ratiopharm
Poland	Imatinib Teva Pharmaceuticals

Portugal	Imatinib ratiopharm
Romania	Imatinib Teva Pharma
Slovakia	Imatinib ratiopharm
Slovenia	Imatinib ratiopharm
Spain	Imatinib ratiopharm
Sweden	Imatinib Teva Sweden
United Kingdom	Imatinib Teva UK

**This leaflet was last revised in July 2014.**