20 mm

115 mm

Package leaflet: Information for the user Imatinib 100 mg Hard Capsules

Imatinib 400 mg Hard Capsules 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 -What Imatinib is and what it is used for -

What you need to know before you

Children and adolescents

How to take Imatinib Possible side effects How to store Imatinib

take Imatinib

Contents of the pack and other information

What Imatinib is and what it is

used for Imatinib capsules are 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 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 start growing out of control.

abnormal white cells (named myeloid cells) 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 inhibits the growth of these cells

Imatinib 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 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 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

beneath the skin in which some cells start growing out of control. Imatinib inhibits the growth of these cells In the rest of this leaflet, we will use the abbreviations when talking about If you have any questions about how Imatinib

Dermatofibrosarcoma protuberans

(DFSP). DFSP is a cancer of the tissue

organs

works or why this medicine has been prescribed for you, ask your doctor 2. What you need to know before

you take Imatinib Imatinib 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: 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. 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: 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 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,

damage to blood vessels known as thrombotic microangiopathy (TMA). If any of these apply to you, tell your doctor before taking Imatinib. You may become more sensitive to the sun

contact your doctor. This may be a sign of

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, tell your doctor straight away if you put on weight very

quickly. Imatinib may cause your body to retain

while taking Imatinib. It is important to cover

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

water (severe fluid retention)

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

day.

Very common (may affect more than 1 in 10 people): headache or feeling tired

diarrhoea or indigestion

bone pain, during imatinib treatment or after you have stopped taking imatinib

swelling such as round your ankles or weight gain If any of these affect you severely, tell your doctor.

of taste

feeling dizzy or weak difficulty in sleeping (insomnia) discharge from the eye with itching,

nose bleeds pain or swelling in your abdomen, unusual hair loss or thinning

dry mouth, dry skin or dry eye hot flushes, chills or night sweats

Not known (frequency cannot be estimated from the available data): reddening and/or swelling on the palms of

slowing of growth in children and adolescents If any of these affect you severely, tell your

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

Reporting of side effects

MHRA Yellow Card in the Google Play or Apple help provide more information on the safety of

Do not use this medicine after the expiry date which is stated on the carton after Do not store above 30°C.

reach of children.

protect from moisture. Do not use any pack that is damaged or

wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

other information What Imatinib capsules contain

The other ingredients are sodium stearyl fumarate and crospovidone (Type A). The capsule shell is composed of gelatin, sodium laurilsulfate and titanium dioxide (E171); additional for 100 mg capsules: iron oxide, yellow (E172) and iron oxide, red (E172) additional for 400 mg capsules: iron oxide, yellow (E172), iron oxide, red (E172) and iron oxide, black (E172) The printing ink is composed of iron oxide, red (E172), shellac, propylene glycol and ammonia solution, concentrated. What Imatinib capsules look like and

brownish yellow colour granular powder in an orange to grayish-orange opaque capsule imprinted with 'RDY' on cap and '100' on body with red ink. They are supplied in packs containing 24, 30, 48, 60, 96, 120 and 180 capsules, but these may not all be available in Imatinib 400 mg capsules contain off- white to

capsule imprinted with 'RDY' on cap and '400' on body with red ink. They are supplied in packs containing 10, 30, 60 and 90 capsules, but these may not all be available in your **Marketing Authorisation Holder and** Manufacturer__ Dr. Reddy's Laboratories (UK) Ltd.,

6 Riverview Road, Beverley, East Yorkshire,

This leaflet was last revised in 04/2022.

HU17 0LD, United Kingdom

Imatinib 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

5 mm

30

30 mm

30 mm

30 mm

30 mm

30

30

30

30 mm

30

30 mm

30 mm

30 mm

30 mm

30 mm

Some children and adolescents taking Imatinib may have slower than normal-growth. Thedoctor will monitor the growth at regular visits.

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

This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free' 3. How to take Imatinib

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

Your doctor has prescribed Imatinib because

you suffer from a serious condition. Imatinib

doctor or-pharmacist tells you-to. Check with your doctor or pharmacist if you are not sure. Do not stop taking Imatinib 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 to take Use in adults Your doctor will tell you exactly how many capsules of Imatinib 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 1 capsule of

600 mg to be taken as 1 capsule of

400 mg (or 4 capsules of 100 mg)

once a day

400 mg plus 2 capsules of 100 mg (or 6 capsules of 100 mg) once a day. If you are being treated for GIST: The starting dose is 400 mg, to be taken as 4 capsules of 100 mg (or 1 capsule of 400 mg) once a day. For CML and GIST, your doctor may prescribe a higher or lower dose depending on how you respond!

to treatment. If your daily dose is 800 mg, you should take a half dose (1 capsule of 400 mg or 4 capsule of 100 mg) in the morning and a half dose (1 capsule of 400 mg or 4 capsule of 100 mg) in the evening. If you are being treated for Ph-positive ALL: The starting dose is 600 mg to be taken as 1 capsule of 400 mg plus 2 capsules of 100 mg (or 6 capsules of 100 mg) once a

If you are being treated for MDS/MPD: The starting dose is 400 mg to be taken as e.g. 1 capsule of 400 mg (or 4 capsules of 100 mg) once a day. If you are being treated for HES/CEL: The starting dose is 100 mg, to be taken

as 1 capsule of 100 mg once a day. Your doctor may decide to increase the dose to 400 mg, to be taken as 1 capsule of 400 mg (or 4 capsules of 100 mg) once a day, depending on how you respond to If you are being treated for DFSP: The dose is 800 mg per day, to be taken as a half dose (1 capsule of 400 mg or 4

capsules of 100 mg) in the morning and a

half dose (1 capsule of 400 mg or 4 capsules of 100 mg) in the evening. Use in children and adolescents The doctor will tell you how many capsules of Imatinib to give to your child. The amount of Imatinib 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 Take Imatinib with a meal. This will help protect you from stomach problems when

taking Imatinib. 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 you can open them up 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

skin-eye contact or inhalation. You should wash your hands immediately after opening the capsules. How long to take Imatinib Keep taking Imatinib every day for as long as your doctor tells you. If you take more Imatinib than you should

contents with caution in order to avoid

capsules, talk to your doctor straight away. You may require medical attention. Take the medicine pack with you. If you forget to take Imatinib If you forget a dose, take it as soon as you

If you have accidentally taken too many

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.

this medicine, ask your doctor, pharmacist 4. Possible side effects Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have any further questions on the use of

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 may cause your body to retain water (severe fluid retention)

signs of infection such as fever, severe chills, sore throat or mouth ulcers. Imatinib 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) 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

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

heartbeat, clouding of urine, tiredness

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:

feeling sick (nausea), being sick (vomiting), muscle cramps or joint, muscle or

Common (may affect up to 1 in 10 people): anorexia, weight loss or a disturbed sense

redness and swelling (conjunctivitis), watery eyes or having blurred vision flatulence, heartburn or constipation

numbness of the hands or feet mouth ulcers joint pain with swelling decreased or increased skin sensitivity If any of these affect you severely, tell your doctor.

the hands and soles of the feet which may be accompanied by tingling sensation and burning pain painful and/or blistering skin lesions doctor.

also report side effects directly via the Yellow Card Scheme, website www.mhra.gov.uk/yellowcard or search for App Store. By reporting side effects you can 5. How to store Imatinib Keep this medicine out of the sight and

Store in the original package in order to shows signs of tampering. Do not throw away any medicines via

Contents of the pack and

The active substance is imatinib mesilate. Each capsule of Imatinib contains either 100 mg or 400 mg imatinib (as mesilate) for 100 mg or 400 mg capsules.

contents of the pack Imatinib 100 mg capsules contain off-white to

brownish yellow color granular powder in a very dark-yellow-to brownish-orange opaque

Dr.Reddy's Artwork **Version No: Submission** DR Reddy's **Brand:** UK **Product Name:** Imatinib Strength: 100/400 mg Form: Capsules Leaflet Pack Size: N/A **Date Created:** 28 Sep 2017 Date Modified: 20 Apr 2022 Project: **Previous DR No:** N/A Previous Material 150089300 Commercial DR No: DRUGS Code: N/A Material Code: N/A Third Party Material Code: N/A N/A **Barcode Number:**

CC1000079922 N/A Magnification: 11106 Pharmacode No: 2022 Implementation Date: Technical Information

Min Font Size: 9 pt Printer India 140 x 510 mm

Colours

Dr.Reddy's Good Health Can't Wait

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