PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

## Imatinib Teva 100 mg

Film-coated tablets Composition. Each film-coated tablet contains: Imatinib (as mesvlate) 100 mg

## Imatinib Teva 400 mg

Film-coated tablets Composition: Each film-coated tablet contains: Imatinib (as mesylate) 400 mg

For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional information"

Read the entire leaflet carefully before using the medicine. Keep this leaflet. You may have to read it again. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist. This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar

## 1. What is the medicine intended for?

Imatinib Teva is a medicine that contains the active ingredient imatinib. The medicine works by inhibiting the production of abnormal cells in the diseases listed below, some of which are certain types of cancer

Imatinib Teva is intended for the treatment of adults and children aged 3 and above with Philadelphia chromosome-positive chronic myeloid leukemia, in the chronic phase, accelerated phase or blast crisis phase.

Imatinib Teva is intended for the treatment of adults with Kit (CD117)-positive malignant metastatic and/or unresectable gastrointestinal stromal tumors (GIST).

Imatinib Teva is intended as an adjuvant treatment in adults after complete surgical resection of the Kit (CD117)-positive gastrointestinal stromal tumor (GIST).

Imatinib Teva is intended for the treatment of adults with diagnosed Philadelphia chromosome-positive newly acute lymphoblastic leukemia (ALL), in combination with chemotherapy.

Imatinib Teva is intended for the treatment of adults with relapsed or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL), as monotherapy.

Imatinib Teva is intended for the treatment of adults with unresectable dermatofibrosarcoma protuberans (DFSP) and of adults with recurrent and/or metastatic DFSP, who are not eligible for surgery.

Imatinib Teva is intended for the treatment of adults with myeloproliferative or myelodysplastic diseases (MPD/MDS), associated with genetic changes in the receptor PDGFR

Imatinib Teva is intended for the treatment of adults with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL), with or without a mutation in FIP1L1-PDGFR $\alpha$ fusion kinase.

Imatinib Teva is intended for the treatment of adults with aggressive systemic mastocytosis (ASM), without the D816V c-kit mutation.

### Therapeutic class: antineoplastic.

Chronic myeloid leukemia (CML) is a cancer of the white blood cells. White blood cells usually help the body to fight infections. In CML-type leukemia, certain abnormal white blood cells (called myeloid cells) start to grow uncontrollably.

GIST are cancerous tumors of the stomach and the intestines They arise as a result of uncontrolled growth of cells in the tissues that support these organs

Acute lymphoblastic leukemia (ALL) of the type that is positive for the Philadelphia chromosome is a cancer of the white blood cells. White blood cells usually help the body to fight infections. In ALL-type leukemia, certain abnormal white blood cells (called lymphoblastic cells) start to grow uncontrollably. Imatinib Teva inhibits the growth of these cells

Dermatofibrosarcoma protuberans (DFSP) is a malignant tumor of the tissue beneath the skin in which some of its cells start to grow uncontrollably. Imatinib Teva inhibits the growth of these

Myeloproliferative or myelodysplastic diseases (MPD/MDS) are a group of blood diseases in which certain blood cells start to grow uncontrollably. Imatinib Teva inhibits the growth of these cells in a certain subtype of these diseases.

Hypereosinophilic syndrome or chronic eosinophilic leukemia (HES/CEL) are a group of blood diseases in which certain blood cells (called eosinophils) start to grow uncontrollably. Imatinib Teva inhibits the growth of these cells in a certain subtype of these diseases.

Aggressive systemic mastocytosis (ASM) are malignant tumors that cause the body to produce too many blood cells called mast cells

# 2. Before using the medicine

Do not use this medicine if:

You are allergic (hypersensitive) to imatinib or to any of the additional ingredients the medicine contains, which are detailed in section 6 "Additional information" of this leaflet. If this applies to you, tell your doctor without taking Imatinib Teva

If you think you may be allergic, but are uncertain, consult vour doctor.

#### Special warnings regarding the use of the medicine Before treatment with Imatinib Teva, tell the doctor if:

- · You are suffering or have suffered in the past from a liver kidnev or heart problem
- You are taking the medicine levothyroxine due to removal of the thyroid
- You have ever had, or might now have, hepatitis B. This is because Imatinib Teva can cause hepatitis B to become active again, which in certain cases can lead to death. Patients will be carefully checked by their doctor to detect signs of this inflammation before starting treatment.
- If you experience bruising, bleeding, fever, fatigue and confusion during treatment with Imatinib Teva, contact your doctor. This may be a sign of damage to blood vessels known as thrombosis of the small blood vessels (thrombotic microangiopathy - TMA).

If any of these applies to you, tell the doctor before taking Imatinib Teva.

You may become more sensitive to the sun during treatment with Imatinib Teva. 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.

Imatinib Teva treatment will only be prescribed by a doctor with experience in medicines for treating blood cancer or solid tumors

Follow the doctor's instructions carefully, even if they differ from the general information that appears in this leaflet.

During treatment with Imatinib Teva, inform the doctor immediately if you gain weight quickly. Imatinib Teva may cause your body to retain water (severe fluid retention)

During treatment with Imatinib Teva, your doctor will regularly check if the medicine is effective. Likewise, the doctor will ask you to undergo blood tests and be weighed regularly.

Children and adolescents (below 18 years of age) Imatinib Teva is given to children from the age of 3 and above for CML disease. For all other indications, Imatinib Teva is not ntended for children and adolescents under 18 years of age.

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

## Tests and follow-up

The doctor will monitor your condition regularly, to check whether the desired effect of treatment with Imatinib Teva is being obtained. You will be asked to have regular blood tests in order to see how you tolerate Imatinib Teva (for example: blood cell count, liver and kidney function, thyroid function).

You should be weighed regularly during the course of treatment with Imatinib Teva

## Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Certain medicines taken together with Imatinib Teva can interfere with its activity. They may increase or decrease the activity of Imatinib Teva, lead to worsening of the side effects or impair the effectiveness of Imatinib Teva. Imatinib Teva may do the same to some other medicines.

Tell the doctor especially if you are taking:

#### Medicines which may increase the level of Imatinib Teva in the blood:

Certain medicines for the treatment of AIDS (HIV), such as: indinavir, lopinavir/ritonavir, ritonavir, saquinavir or nelfinavir; Certain medicines for the treatment of hepatitis C, such as: telaprevir or boceprevir:

Certain medicines for the treatment of fungal infections such as: ketoconazole, itraconazole, posaconazole, voriconazole; Certain medicines for the treatment of bacterial infections, such

as: erythromycin, clarithromycin or telithromycin; Exercise caution if you are taking a medicine that may increase

the levels of Imatinib Teva in the blood

Medicines which may decrease the levels of Imatinib Teva in the blood:

## Dexamethasone, an anti-inflammatory steroidal medicine;

Certain medicines for the treatment of epilepsy, such as: phenytoin, carbamazepine, oxcarbazepine, phenobarbital, fosphenytoin or primidone:

Rifampicin, a medicine for the treatment of tuberculosis

Hypericum perforatum (also known as St. John's Wort) - a herbal remedy for the treatment of depression and other conditions:

Avoid using the medicines listed above during the course of treatment with Imatinib Teva. If you are taking any of the medicines mentioned above, your doctor may prescribe alternative medicines for you.

#### Medicines whose blood levels may increase due to use of Imatinib Teva:

Cyclosporine - an immunosuppressant medicine:

Warfarin – a medicine for the treatment of blood coagulation

disorders (such as blood clots and thrombosis) or other medicines for the treatment of blood coagulation disorders: Tacrolimus sirolimus - medicines to prevent rejection of a

the eyes or skin (signs of liver disorders)

transplanted organ in patients who have undergone organ transplantation. Fentanyl, alfentanil – medicines for the treatment of pain;

Terfenadine – for the treatment of allergy;

Bortezomib, docetaxel - medicines for the treatment of cancer; Quinidine:

Certain medicines for the treatment of high cholesterol levels from the statin family, such as: simvastatin;

Certain medicines for the treatment of mental disorders. such as: benzodiazenines or nimozide:

Certain medicines for the treatment of hypertension or heart disorders, such as: calcium channel blockers or metoprolol; Ergotamine, diergotamine – for the treatment of migraine; Paracetamol

### Medicines whose blood levels may decrease following use of Imatinib Teva:

Levothyroxine - a medicine given following removal of the thyroid gland.

In addition, inform the doctor if you are taking Imatinib Teva and you have been prescribed a new medicine, including nonprescription medicines, which you have not taken previously during Imatinib Teva treatment

## Use of the medicine and food

Take Imatinib Teva with a meal to protect the stomach Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, consult a doctor before using the medicine

Imatinib Teva is not recommended for use during pregnancy unless clearly necessary, as it may harm your baby. Your doctor will discuss with you the risks associated with taking Imatinib Teva during pregnancy.

Women of childbearing age should use effective contraception during treatment with Imatinib Teva and for 15 days after the end of treatment.

Do not breastfeed during treatment with Imatinib Teva and for 15 days after the end of treatment, as it may harm your baby. Patients who are concerned about their fertility during treatment with Imatinib Teva should consult the doctor

## Driving and operating machinery

If you feel dizzy or drowsy, or if you have blurred vision while taking Imatinib Teva, do not drive a vehicle and do not operate tools or machinery, until you feel well.

Children should be cautioned against riding a bicycle or playing near a road etc

#### Important information about some of the ingredients of the medicine

This medicine contains lactose.

Imatinib Teva 100 mg: each tablet contains 27.5 mg lactose. Imatinib Teva 400 mg: each tablet contains 110 mg lactose. If you have an intolerance to certain sugars, inform the doctor before taking this medicine.

This medicine contains sodium

Imatinib Teva 100 mg: each tablet contains approximately 1.7 mg sodium.

Imatinib Teva 400 mg: each tablet contains approximately 7 mg sodium

This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free The medicine contains FD&C YELLOW #6/SUNSET YELLOW

FCF which may cause allergic reactions.

## 3. How should you use the medicine?

The doctor has prescribed Imatinib Teva for you because you suffer from a serious illness. Imatinib Teva may help you fight this illness.

Always use the medicine according to the doctor's instructions. It is important that you do this as long as the doctor instructs you to. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

Use in adults

400 mg in the evening.

diseases (MPD/MDS):

eosinophilic leukemia (HES/CEL):

The doctor will tell you exactly how many tablets of Imatinib Teva you should take.

#### For the treatment of chronic myeloid leukemia (CML): Depending on your condition, the recommended dosage is 400

mg or 600 mg to be taken once a day.

For the treatment of malignant tumors of the stomach and the intestines (GIST): The recommended dosage is 400 mg to be taken once a day.

For the treatment of CML and GIST diseases, your doctor

may prescribe a higher or lower dosage, depending on how

vou respond to the treatment. If your doctor decides on a daily

dosage of 800 mg, you need to take 400 mg in the morning and

For the treatment of acute lymphoblastic leukemia (ALL) of

the type that is positive for the Philadelphia chromosome:

For the treatment of myeloproliferative or myelodysplastic

The recommended dosage is 400 mg to be taken once a day.

The recommended dosage is 400 mg to be taken once a day.

In some cases the doctor may recommend an initial dosage of

100 mg once a day, and if necessary the doctor will consider

For the treatment of hypereosinophilic syndrome or chronic

The recommended dosage is 600 mg to be taken once a day.

| increasing the dosage to 400 mg once a day, depending on   | burning sensation, pustular eruption (signs of a skin disorder)  |
|--|--|
| your response to the treatment.  | · Severe abdominal pain, vomiting blood, black or bloody   |
| For the treatment of dermatofibrosarcoma protuberans   | stools (signs of gastrointestinal disorders)   |
| ( <b>DFSP</b> ):<br>The recommended dosage is 800 mg per day, to be taken as   | <ul> <li>Blood in the urine</li> <li>Severely decreased urine output (sign of kidney disorders)</li> </ul>   |
| 400 mg in the morning and 400 mg in the evening.   | <ul> <li>Nausea with diarrhea and vomiting, abdominal pain or fever</li> </ul>   |
| For the treatment of aggressive systemic mastocytosis  | (signs of intestinal function disorders)   |
| (ASM):   | • Severe headache, weakness or paralysis of the limbs or face,   |
| The recommended dosage is 400 mg once a day.   | difficulty speaking, sudden loss of consciousness (signs of a  |
| In some cases the doctor may recommend an initial dosage of  | nervous system disorder such as bleeding or swelling in the  |
| 100 mg <b>once</b> a day, and if necessary the doctor will consider increasing the dosage to 400 mg <b>once</b> a day, depending on  | <ul> <li>skull/brain)</li> <li>Pale skin, tiredness, shortness of breath and dark urine</li> </ul>   |
| your response to the treatment.  | (signs of low levels of red blood cells)   |
| A 400 mg dosage can be taken either as one tablet of 400 mg  | Eye pain or decreased vision, bleeding in the eyes   |
| or four tablets of 100 mg.   | Pain in the hips or difficulty walking   |
| A 600 mg dosage is to be taken as one tablet of 400 mg plus  | Numb or cold fingers and toes (signs of Raynaud's syndrome)  |
| two tablets of 100 mg.   | <ul> <li>Sudden swelling and redness of the skin (signs of a skin<br/>inflammation called callulitie)</li> </ul>   |
| The dosage determined by the doctor may vary depending on your response to the treatment.  | <ul><li>inflammation called cellulitis)</li><li>Difficulty hearing</li></ul>   |
| Use in children and adolescents  | <ul> <li>Muscle weakness and muscle spasms accompanied by an</li> </ul>  |
| The doctor will instruct you how many tablets of Imatinib Teva   | abnormal heart rate (signs of changes in blood potassium   |
| to give to your child. The dosage of Imatinib Teva that will be  | level)   |
| given depends on the child's condition, body weight and height.  | Signs of bruising     Abdominal pain with pausage  |
| For CML patients, the maximum dosage in children must not exceed 600 mg.   | <ul> <li>Abdominal pain with nausea</li> <li>Muscle spasms with a fever, red-brown urine, muscle pain or</li> </ul>  |
| The treatment can be given to your child either as a once-   | weakness (signs of muscle disorders)   |
| daily dose or alternatively the daily dose can be split into two   | Pelvic pain sometimes accompanied by nausea and vomiting   |
| administrations (half in the morning and half in the evening).   | with unexpected vaginal bleeding, feeling dizzy or fainting  |
| Do not exceed the recommended dose.  | due to low blood pressure (signs of an ovarian or uterine  |
| Duration of treatment<br>Take Imatinib Teva every day until your doctor instructs you to   | <ul> <li>disorder)</li> <li>Nausea, shortness of breath, irregular heartbeat, cloudy</li> </ul>  |
| stop.  | urine, tiredness and/or joint discomfort accompanied   |
| How to take the medicine   | by abnormal values in laboratory test results (e.g., high  |
| Take Imatinib Teva with a meal. Taking Imatinib Teva with a  | potassium, uric acid and calcium levels and low phosphorous  |
| meal will help protect against stomach problems while taking   | levels in the blood)   |
| Imatinib Teva.<br>Swallow the tablets whole with a large glass of water. If  | <ul> <li>Blood clots in small blood vessels (thrombosis of the small<br/>blood vessels)</li> </ul>   |
| necessary, the tablets may be halved at the score line.  | Side effects of unknown frequency (side effects whose  |
| If you are unable to swallow the tablets, you can dissolve them  | frequency has not yet been determined):  |
| in a glass of water or apple juice in the following manner:  | • A combination of a widespread severe rash, nausea, fever,  |
| Use approximately 50 ml of water for each 100 mg tablet or   | high levels of certain white blood cells or yellow skin or eyes  |
| <ul><li>200 ml of water for each 400 mg tablet.</li><li>Stir with a teaspoon until complete dissolution of the tablet(s).</li></ul>  | (signs of jaundice) with shortness of breath, chest pain/<br>discomfort, severely decreased urine output and a feeling of  |
| • Once dissolved, drink the entire contents of the glass   | thirst (signs of a treatment-related allergic reaction)  |
| immediately. Traces of the dissolved tablet(s) may remain in   | Chronic renal failure  |
| the glass.   | · Recurrence (reactivation) of hepatitis B, if you have had  |
| If you accidentally took a higher dosage   | hepatitis (a liver infection) in the past  |
| If you took an overdose or if a child accidentally swallowed   | If you experience any of these side effects, refer to the doctor   |
|  |  |
| this medicine, go to the doctor or the emergency room of the   | immediately.   |
| hospital immediately and take the package of the medicine with   | Additional side effects:   |
|  |  |
| hospital immediately and take the package of the medicine with<br>you. You may require medical supervision.<br>If you have forgotten to take the medicine<br>If you have forgotten to take this medicine at the required time,   | Additional side effects:<br>Refer to a doctor if any of the side effects listed below<br>affects you severely:<br>Very common side effects (side effects that occur in more  |
| hospital immediately and take the package of the medicine with<br>you. You may require medical supervision.<br>If you have forgotten to take the medicine<br>If you have forgotten to take this medicine at the required time,<br>take it as soon as you remember. However, if it is nearly time for   | Additional side effects:<br>Refer to a doctor if any of the side effects listed below<br>affects you severely:<br>Very common side effects (side effects that occur in more<br>than 1 out of 10 users):  |
| hospital immediately and take the package of the medicine with<br>you. You may require medical supervision.<br>If you have forgotten to take the medicine<br>If you have forgotten to take this medicine at the required time,<br>take it as soon as you remember. However, if it is nearly time for<br>the next dose, do not take the forgotten dose. Continue taking   | Additional side effects:<br>Refer to a doctor if any of the side effects listed below<br>affects you severely:<br>Very common side effects (side effects that occur in more<br>than 1 out of 10 users):<br>• Headache or feeling tired   |
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swallowing, increased sweating, skin discoloration, breaking peeling skin, fever, raised red or purple skin patches, itching, of the fingernails and toenails, inflammation of the hair follicle.

thickened red patches around the elbows and knees, darkening of the skin breast enlargement in men and women edema of the testicles erection disorder heavy or irregular menstrual period, decreased libido, pain in the nipples, chest pain. general malaise, viral infection such as a cold sore, back pain resulting from kidney disorder, increased frequency of urination, ncreased appetite, stomach ulcer, joint and muscle stiffness, abnormal laboratory test results, swelling of the lymph nodes. Rare side effects (side effects that occur in 1-10 out of 10,000 users):

Confusion, nail discoloration, fungal infection, cardiac arrest, convulsions, glaucoma, cataract, arthritis

Side effects of unknown frequency (side effects whose frequency has not yet been determined):

- Reddening and/or swelling of the palms of the hands and soles of the feet, which may be accompanied by a tingling sensation and burning pain
- Skin lesions which are painful and/or covered with blisters
- Slowed growth in children and adolescents

### Side effects in patients with aggressive systemic mastocvtosis:

All patients with aggressive systemic mastocytosis (ASM) have experienced at least one side effect at some point.

The most frequently reported side effects were: diarrhea. nausea, ascites, muscle cramps, shortness of breath, tiredness, peripheral edema, anemia, itching, rash and inflammation of the lower respiratory tract.

## If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet. consult your doctor

### Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects health gov il

## 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month
- Store in a dry place at a temperature below 25°C. The medicine should be stored in the original package. Bottle package: caution! The bottle contains a desiccant. do not swallow! Do not take the desiccant out of the bottle. The medicine can be used for up to 60 days after first opening the bottle, but no later than the expiry date.
- Do not use if the package is damaged or shows signs of tampering.
- Do not discard medicines in wastewater or a domestic trash can. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment

## 6. Additional information

#### In addition to the active ingredient the medicine also contains:

Microcrystalline cellulose, lactose monohydrate,

croscarmellose sodium, colloidal silicon dioxide, crospovidone, magnesium stearate, hypromellose, hydroxypropyl cellulose, sodium stearyl fumarate, talc, titanium dioxide, iron oxide vellow, FD&C yellow no.6.

#### What does the medicine look like and what are the contents of the package

Imatinib Teva 100 mg: a plastic bottle containing 60 orangebrown film-coated round shaped tablets. One side of the tablets is scored and embossed with "TE" to the left of the score line and with "VA" to the right. The other side of the tablets is embossed with the number "7629".

The bottle contains a desiccant which is not to be swallowed. It should be left inside the bottle in order to protect the tablets from humiditv

Imatinib Teva 400 mg: a plastic bottle containing 30 orangeprown, film-coated, caplet shaped tablets. One side of the tablets is scored and embossed with "TE" to the left of the score line and with "VA" to the right. The other side of the tablets is embossed with the number "7630"

The bottle contains a desiccant which is not to be swallowed. It should be left inside the bottle in order to protect the tablets from humidity

Name and address of the manufacturer and marketing authorization holder

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020. The leaflet was revised in November 2021 in accordance with

the Ministry of Health guidelines.

Registration numbers of the medicine in the national drug registry of the Ministry of Health:

Imatinib Teva 100 mg: 153-98-34034 Imatinib Teva 400 mg: 153-97-34031

MATINIB PIL MW1021

