

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Dasatinib Sandoz® 20 mg Film-coated tablets	Dasatinib Sandoz® 50 mg Film-coated tablets	Dasatinib Sandoz® 70 mg Film-coated tablets
Composition: Each tablet contains: dasatinib 20 mg	Composition: Each tablet contains: dasatinib 50 mg	Composition: Each tablet contains: dasatinib 70 mg

Dasatinib Sandoz® 100 mg Film-coated tablets	Dasatinib Sandoz® 140 mg Film-coated tablets
Composition: Each tablet contains: dasatinib 100 mg	Composition: Each tablet contains: dasatinib 140 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

Dasatinib Sandoz is not intended for use in children and adolescents under the age of 18. There is limited experience with the use of dasatinib in this age group.

1. What is this medicine intended for?

Dasatinib Sandoz is a medicine intended for treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase.
- Chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib mesilate.
- Philadelphia chromosome positive acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.

Therapeutic group: Protein kinase inhibitors.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient (dasatinib) or to any of the other ingredients in this medicine (see section 6 'Additional information').
- If you could be allergic, contact your doctor for advice.**

Special warnings about using this medicine

Inform your doctor or pharmacist before treatment with Dasatinib Sandoz if:

- you are taking **medicines to thin the blood** or prevent clots (see "Drug interactions").
- you have a liver or heart problem, or used to have one.
- **you start having difficulty breathing, chest pain, or a cough** during treatment with Dasatinib Sandoz, contact your doctor. This may be a sign of fluid retention in the lungs or chest (which can be more common in patients aged 65 years and older), or due to changes in the blood vessels supplying blood to the lungs.
- you have ever had or now have a hepatitis B infection. This is because Dasatinib Sandoz 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.
- bruising, bleeding, fever, fatigue and confusion appear when taking Dasatinib Sandoz, contact your doctor. These may be signs of damage to blood vessels known as thrombotic microangiopathy (TMA).

Children and adolescents

Dasatinib Sandoz is not intended for use in children and adolescents under the age of 18. There is limited experience with the use of dasatinib in this age group.

Tests and follow-up

Your doctor will regularly monitor your condition to check whether Dasatinib Sandoz is having the desired effect.

During treatment with this medicine, you will also have blood tests regularly to monitor the progress of treatment.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Dasatinib Sandoz is mainly cleared by the liver. Certain medicines may interfere with the effect of Dasatinib Sandoz when taken together.

Do not take the following medicines together with Dasatinib Sandoz:

- Ketoconazole and itraconazole - these are **antifungal** medicines
- erythromycin, clarithromycin and telithromycin - these are **antibiotics**
- ritonavir - this is an **antiviral** medicine
- phenytoin, carbamazepine, phenobarbital - for treatment of **epilepsy**
- rifampicin - this is a treatment for **tuberculosis**
- famotidine and omeprazole - these are medicines that **block stomach acids**
- St. John's wort - a herbal preparation for treatment of **depression** (also known as Hypericum perforatum)

Do not take medicines that neutralise stomach acids (**antacids** such as aluminium hydroxide or magnesium hydroxide **for treatment of heartburn**) in the **2 hours before or 2 hours after taking Dasatinib Sandoz.**

Tell your doctor if you are taking **medicines to thin the blood** or prevent clots.

Using this medicine and food

You can take this medicine with or without food.

Do not take this medicine with grapefruit or grapefruit juice.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, **tell your doctor immediately.**

Dasatinib Sandoz is not to be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risk of taking Dasatinib Sandoz during pregnancy. Both men and women taking dasatinib Sandoz should consult their doctor regarding use of effective contraception during treatment.

If you are breast-feeding, tell your doctor. You should stop breast-feeding while you are taking Dasatinib Sandoz.

Driving and using machines

Take special care when driving or using machines in case you experience side effects such as dizziness and blurred vision.

Important information about some of this medicine's ingredients

Dasatinib Sandoz contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to use this medicine?

Dasatinib Sandoz will only be prescribed to you by a doctor with experience in treating leukaemia. Always use Dasatinib Sandoz according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Dasatinib Sandoz is intended for adults.

Only your doctor will determine your dose and how you should take this medicine.

Take this medicine according to the dosage and for the period of time determined by your doctor. Depending on how you respond to the treatment, your doctor will inform you if a higher or lower dose of Dasatinib Sandoz is necessary or even if treatment should be briefly stopped. For higher or lower doses, you may need to take combinations of the different tablet strengths.

Do not exceed the recommended dose.

Treatment duration -

Take Dasatinib Sandoz daily until your doctor tells you to stop. Make sure you take Dasatinib Sandoz for as long as it is prescribed for you.

Take the medicine at the same time every day.

Swallow the tablets whole. Do not crush, split or chew the tablets (to ensure the consistency of the dosage and lower the risk of skin exposure). Do not disperse the tablets (because in patients who received a tablet that was dispersed, the exposure is lower than in patients who swallowed the tablet whole).

You cannot be sure you will receive the correct dose if you crush, split, chew or disperse the tablets.

You can take this medicine with or without food. Do not take this medicine with grapefruit or grapefruit juice.

If you also take antacids (to treat heartburn) such as aluminium hydroxide or magnesium hydroxide - take the antacids no less than two hours before or two hours after Dasatinib Sandoz.

Special handling instructions for Dasatinib Sandoz

It is unlikely that the Dasatinib Sandoz tablets will get broken. But if that happens, persons other than the patient should use gloves when handling Dasatinib Sandoz.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Even if your health improves, do not stop treatment without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. **Wear glasses if you need them.**

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, use of Dasatinib Sandoz may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Consult your doctor immediately if the following effects appear, as they may be signs of serious side effects:

- Appearance of chest pain, difficulty breathing, coughing and fainting
- **Unexpected bleeding or bruising** without having an injury
- Appearance of blood in your vomit, stools or urine, or appearance of black stools
- Appearance of **signs of infection** such as fever, severe chills
- Appearance of fever, sore throat or mouth, blistering or peeling of your skin and/or mucous membranes

Additional side effects:

Very common side effects (may affect more than 1 in 10 users):

- **Infections** (including bacterial, viral and fungal)
- **Heart and lungs:** shortness of breath
- **Digestive problems:** diarrhoea, nausea, vomiting
- **Skin, hair, eye, general:** skin rash, fever, swelling around the face, hands and feet, headache, feeling tired or weak, bleeding
- **Pain:** pain in the muscles (during or after discontinuing treatment), abdominal pain
- **Tests may show:** low blood platelet count, low white blood cells count (neutropaenia), anaemia, fluid around the lungs

Common side effects (may affect up to 1 in 10 users):

- **Infections:** pneumonia, herpes virus infection (including cytomegalovirus-CMV), upper respiratory tract infection, serious infection of the blood or tissues (including uncommon cases with fatal outcomes)
- **Heart and lungs:** palpitations, irregular heartbeat, congestive heart failure, weak heart muscle, high blood pressure, increased blood pressure in the lungs, cough
- **Digestive problems:** appetite disturbances, taste disturbance, bloated or distended abdomen, inflammation of the colon, constipation, heartburn, mouth ulceration, weight increase, weight decrease, gastritis
- **Skin, hair, eye, general:** skin tingling, itching, dry skin, acne, inflammation of the skin, persistent noise in ears, hair loss, excessive perspiration, visual disorder (including blurred vision and disturbed vision), dry eye, bruise, depression, insomnia, flushing, dizziness, bruising, anorexia, somnolence, generalised oedema
- **Pain:** pain in joints, muscular weakness, chest pain, pain around hands and feet, chills, stiffness in muscles and joints, muscle spasm
- **Tests may show:** fluid around the heart, fluid in the lungs, arrhythmia, febrile neutropaenia, gastrointestinal bleeding, high uric acid levels in the blood

Uncommon side effects (may affect up to 1 in 100 users):

- **Heart and lungs:** heart attack (including fatal outcomes), inflammation of the lining (fibrous sack) surrounding the heart, irregular heartbeat, chest pain due to lack of blood supply to the heart (angina), low blood pressure, narrowing of airway that may cause breathing difficulties, asthma, increased blood pressure in the arteries (blood vessels) of the lungs, blood clots
- **Digestive problems:** inflammation of the pancreas, peptic ulcer, inflammation of the food pipe, swollen abdomen, tear in the skin of the anal canal, difficulty in swallowing, inflammation of the gallbladder, blockage of bile ducts, gastro-oesophageal reflux (a condition where acid and other stomach contents come back up into the throat)
- **Skin, hair, eye, general:** allergic reaction including tender, red lumps on the skin (erythema nodosum), anxiety, confusion, mood swings, lower sexual drive, fainting, tremor, inflammation of the eye which causes redness or pain, a skin disease characterized by tender, red, well-defined blotches with the sudden onset of fever and raised white blood cell count (neutrophilic dermatosis), loss of hearing, sensitivity to light, visual impairment, increased eye tearing, change in skin colour, inflammation of fatty tissue under the skin, skin ulcer, blistering of the skin, change in nails, change in hair, hand-foot disorder, renal failure, urinary frequency, breast enlargement in men, menstrual disorder, general weakness and discomfort, low thyroid function, losing balance while walking, osteonecrosis (a disease of reduced blood flow to the bones, which can cause bone loss and bone death), arthritis, skin swelling anywhere in the body
- **Pain:** inflammation of vein which can cause redness, tenderness and swelling, inflammation of the tendon
- **Brain:** loss of memory
- **Tests may show:** abnormal blood test results and possibly impaired kidney function caused by the waste products of the tumour (tumour lysis syndrome), low levels of albumin in the blood, low levels of lymphocytes (a type of white blood cell) in the blood, high level of cholesterol in the blood, swollen lymph nodes, bleeding in the brain, irregularity of the electrical activity of the heart, enlarged heart, inflammation of the liver, protein in the urine, raised creatine phosphokinase (an enzyme mainly found in the heart, brain and skeletal muscles), raised troponin (an enzyme mainly found in the heart and skeletal muscles), raised gamma-glutamyltransferase (an enzyme mainly found in the liver), appearance of milky fluid around the lungs (chylothorax)

Rare side effects (may affect up to 1 in 1,000 users):

- **Heart and lungs:** enlargement of the right ventricle in the heart, inflammation of the heart muscle, collection of conditions resulting from blockage of blood supply to the heart muscle (acute coronary syndrome), cardiac arrest (stopping of blood flow from the heart), coronary heart disease, inflammation of the tissue covering the heart and lungs, blood clots (in deep veins), blood clots in the lungs
- **Digestive problems:** loss of vital nutrients such as protein from your digestive tract, bowel obstruction, anal fistula (an abnormal opening from the anus to the skin around the anus), impairment of kidney function, diabetes
- **Skin, hair, eye, general:** convulsion, inflammation of the optic nerve that may cause a complete or partial loss of vision, blue-purple mottling of the skin, abnormally high thyroid function, inflammation of the thyroid gland, ataxia (a coordination disorder), difficulty walking, miscarriage, inflammation of the skin blood vessels, skin fibrosis
- **Brain:** stroke, temporary episode of neurologic dysfunction caused by impaired blood flow, facial nerve paralysis, dementia
- **Immune system:** Severe allergic reaction
- **Musculoskeletal and connective tissue:** delayed fusion of the rounded ends that form joints (epiphyses); slower or delayed growth

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- Inflammation of the lungs
- Bleeding in the stomach or bowels that can cause death
- Recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection)
- A reaction with fever, blisters on the skin, and ulceration of the mucous membranes
- Disease of the kidneys with symptoms including oedema and abnormal laboratory test results such as protein in the urine and low protein level in the blood
- Damage to blood vessels known as thrombotic microangiopathy (TMA), including decreased red blood cell count, decreased platelets, and formation of blood clots

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

Storage conditions:

- Store below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Tablet core: lactose monohydrate, cellulose, microcrystalline (E460), croscarmellose sodium, hydroxypropylcellulose (E463), magnesium stearate (E470b)

Film-coating: poly (Vinyl Alcohol) (E1203), titanium dioxide (E171), talc (E553b), glyceryl monostearate (E471), sodium laurilsulfate

What does the medicine look like and what are the contents of the pack?

Dasatinib Sandoz 20 mg: White to off-white, biconvex, round film-coated tablets with "20" debossed on one side.

A blister pack (tray) contains 60 film-coated tablets.

Dasatinib Sandoz 50 mg: White to off-white, biconvex, oval film-coated tablets with "50" debossed on one side.

A blister pack (tray) contains 60 film-coated tablets.

Dasatinib Sandoz 70 mg: White to off-white, biconvex, round film-coated tablets with "70" debossed on one side.

A blister pack (tray) contains 60 film-coated tablets.

Dasatinib Sandoz 100 mg: White to off-white, biconvex, oval film-coated tablets with "100" debossed on one side.

A blister pack (tray) contains 30 film-coated tablets.

Dasatinib Sandoz 140 mg: White to off-white, biconvex, round film-coated tablets with "140" debossed on one side.

A blister pack (tray) contains 30 film-coated tablets.

License Holder and Importer's name and address: Novartis Israel Ltd., P.O.Box 7126, Tel Aviv, Israel.

Revised in June 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Dasatinib Sandoz 20 mg film-coated tablets: 173-07-36528-99

Dasatinib Sandoz 50 mg film-coated tablets: 173-08-36529-99

Dasatinib Sandoz 70 mg film-coated tablets: 173-09-36530-99

Dasatinib Sandoz 100 mg film-coated tablets: 173-10-36531-99

Dasatinib Sandoz 140 mg film-coated tablets: 173-11-36532-99

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