

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DASAMIA (20, 50, 70,100) Film coated tablets

(Dasatinib)

Contains sugar: Lactose monohydrate

Read all of this leaflet carefully before you start taking DASAMIA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DASAMIA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What DASAMIA is and what it is used for

DASAMIA contains the active substance dasatinib. This medicine is used to treat chronic myeloid leukaemia (CML) in adults. Leukaemia is a cancer of white blood cells. These white cells usually help

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 1 of 15

the body to fight infection. In people with CML, white cells called granulocytes start growing out of control. **DASAMIA** inhibits the growth of these leukaemic cells.

DASAMIA is also used to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) and lymphoid blast CML in adults who are not benefiting from prior therapies. In people with ALL, white cells called lymphocytes multiply too quickly and live too long. **DASAMIA** inhibits the growth of these leukemic cells.

2. What you need to know before you take **DASAMIA**

Do not take **DASAMIA**:

- If you are hypersensitive (allergic) to **DASAMIA** or any of the other ingredients of this medicine (listed in section 6).
- Using H2 blockers or proton pump inhibitors with **DASAMIA** is not recommended.

Warnings and precautions

Special care should be taken with **DASAMIA**

- If you are taking medicines to thin the blood or prevent clots (see "**Other medicines and DASAMIA**").
- if you have problems with your immune system
- If you have a liver problem
- If you have a heart problem, including a condition called congenital long QT syndrome.
- If you start having difficulty breathing, chest pain, or a cough when taking **DASAMIA**: 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 the lungs.
- If you have ever had or might now have a hepatitis B infection. This is because **DASAMIA** 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.

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 2 of 15

- If you experience bruising, bleeding, fever, fatigue and confusion when taking **DASAMIA**, contact your doctor. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).
- If you have a history of skin problems.

Cerebrovascular events (conditions that affect blood flow to your brain) including stroke and brain bleed have been reported with the use of this medicines (see **Possible Side Effects**).

Your doctor will regularly monitor your condition to check whether **DASAMIA** is having the desired effect. You will also have blood tests regularly while you are taking **DASAMIA**.

Children and adolescents

DASAMIA has not been studied in children.

Other medicines and DASAMIA

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

DASAMIA is mainly handled by the liver. Certain medicines may interfere with the effect of **DASAMIA** when taken together.

These medicines are not to be used with **DASAMIA**:

- ketoconazole, itraconazole - these are antifungal medicines
- erythromycin, clarithromycin, telithromycin - these are antibiotics
- ritonavir, atazanavir, indinavir, nelfinavir, saquinavir - these are antiviral medicines
- dexamethasone – a corticosteroid medicine
- phenytoin, carbamazepine, phenobarbital - these are treatments for epilepsy
- rifampicin - this is a treatment for tuberculosis
- famotidine, omeprazole - these are medicines that block stomach acids
- St. John's wort - a herbal preparation obtained without a prescription, used to treat depression

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 3 of 15

Do not take medicines that neutralise stomach acids (antacids such as aluminium hydroxide or magnesium hydroxide) in the 2 hours before or 2 hours after taking **DASAMIA**.

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

DASAMIA with food and drink

Do not drink grapefruit juice when you are taking **DASAMIA**.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or other health care provider for advice before taking this medicine.

Sexually active men who take **DASAMIA**, are advised to use a condom to avoid pregnancy in their partner

Women who are pregnant or planning to become pregnant should not take **DASAMIA**. **DASAMIA** may harm the baby when given to a pregnant woman. Women should avoid becoming pregnant while undergoing treatment with **DASAMIA**.

Women of childbearing potential should use effective contraceptive measures while taking **DASAMIA** and for 6 months after you stop taking **DASAMIA**.

If you are a male patient and your female partner could become pregnant, you should use effective contraceptive measure (e,g condom) during treatment with **DASAMIA** and 3 months after taking the last dose of **DASAMIA**.

It is not known if **DASAMIA** can pass into your breast milk or if it can harm your baby. Do not breastfeed if you are taking **DASAMIA**.

Driving and using machines

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 4 of 15

No studies on the effects on the ability to drive and use machines when taking **DASAMIA** have been performed. Take special care when driving or using machines in case you experience side effects such as dizziness and blurred vision.

It is not possible to predict to what extent **DASAMIA** may interfere with your activities. You should ensure that you do not engage in the following activities (e.g. driving, riding, sailing, operating machines / equipment) until you are aware of the measure to which **DASAMIA** affects you.

DASAMIA contains lactose

DASAMIA contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **DASAMIA**.

3. How to take **DASAMIA**

Do not share medicines prescribed for you with any other person.

Always take **DASAMIA** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose for **DASAMIA** in patients with chronic phase CML is 100 mg once daily, with or without a meal.

The recommended starting dose for **DASAMIA** in patients with accelerated, myeloid or lymphoid blast phase CML or Ph+ ALL is 70 mg twice daily, with or without a meal. Try to take **DASAMIA** at the same time each day.

Swallow **DASAMIA** tablets whole. Do not break, cut, chew or crush the tablets.

Depending on your response to treatment and any side effects that you may experience, your doctor may adjust your dose of **DASAMIA** upward or downward, or may temporarily discontinue **DASAMIA**.

Your doctor will tell you how long your treatment with **DASAMIA** will last.

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 5 of 15

You should not change your dose or stop taking **DASAMIA** without first talking with your healthcare provider.

If you take more **DASAMIA** than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take **DASAMIA**

Do not take a double dose to make up for a forgotten tablet. Take the next scheduled dose at the regular time.

If you stop taking **DASAMIA**

Do not stop taking your medicine without consulting your doctor.

4. Possible side effects

DASAMIA can have side effects.

Not all side effects reported for **DASAMIA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DASAMIA** please consult your health care provider for advice.

If any of the following happens, stop taking DASAMIA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe potentially life-threatening allergic reactions symptoms include red-purple swellings on the shins, thighs and, less commonly, the arms. Joint and muscle pains and fever may also occur (anaphylactic shock)
- Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome)

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 6 of 15

- Redness, swelling, and pain on the palms of the hands and/or the soles of the feet, sometimes blisters appear (palmar-plantar erythrodysesthesia syndrome)
- Hypersensitivity (allergic) reactions including skin rash with red lumps
- Severe condition of the skin that may affect the mouth and other parts of the body symptoms include red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea (erythema multiforme)
- Unexpected bleeding or bruising without having an injury
- Gastro-intestinal bleeding, blood in your vomit, stools or urine, or have black stools

These are all very serious side effects. If you have them, you may have had a serious reaction to **DASAMIA**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects

- Chest pain, difficulty breathing, shortness of breath, coughing, wheezing and fainting which may be due to swelling of lungs (pneumonitis) or blood clots in the lungs (pulmonary embolism) or accumulation of fluid between the tissues that line the lungs and the chest (pleural effusion, dyspnoea)
- Tiredness, headaches, dizziness, being short of breath when exercising and looking pale, frequent infections such as fever, severe chills, sore throat or mouth ulcers bleeding or bruising more easily than normal which may be due to a disease of the blood with a reduced number of red or white blood cells or platelets (myelosuppression)

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 7 of 15

- Serious lung infection with fever, chills, cough, phlegm and occasionally blood (pneumonia), herpes virus infection (including cytomegalovirus - CMV), upper respiratory tract infection, serious infection of the blood or tissues (including uncommon cases with fatal outcomes).
- Infection, fever with decrease in the number of a type of white blood cell in the blood (febrile neutropenia)

Less frequent side effects

- Headache, one-sided weakness, vomiting, seizures, decreased level of consciousness, and neck stiffness (CNS bleeding)
- Fatigue, lethargy, and/or abnormal paleness of the skin (pallor) due to anemia, a rare disorder of blood production in which the bone marrow, the spongy tissue in the center of the bones, fails to function in an adequate manner (aplasia pure red cell)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

Infections

- Including bacterial, viral and fungal

Digestive problems

- Diarrhoea, feeling or being sick (nausea, vomiting)

Pain

- Pain in the muscles (during or after discontinuing treatment), tummy (abdominal) pain

General disorders

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 8 of 15

- Swelling around the face, hands and feet, headache, feeling tired or weak

Heart and lungs

- Palpitations, irregular heartbeat
- Congestive heart failure
- Weak heart muscle
- High blood pressure
- Increased blood pressure in the lungs

Digestive problems

- Appetite disturbances, high uric acid levels in the blood, which may cause gout (hyperuricaemia)
- Taste disturbance
- Bloating or distended tummy (abdomen)
- Inflammation of the colon
- Constipation, heartburn, mouth ulceration
- Weight increase, weight decrease
- Inflammation or irritation of the lining of the stomach

Skin, hair, eye, general

- Skin tingling
- Allergic reaction including tender, red lumps on the skin (erythema nodosum)
- Itchy rashes (urticaria), dry skin, acne, inflammation of the skin
- Persistent noise in ears
- Hair loss (alopecia), excessive perspiration or sweating (hyperhidrosis)
- Visual disorder (including blurred vision and disturbed vision), dry eye, bruise
- Depression, insomnia, flushing, dizziness, contusion (bruising), anorexia, sleepiness (somnolence), generalised oedema

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 9 of 15

Pain

- Pain in joints (arthralgia)
- Muscular weakness/pain (myalgia)
- Pain around hands and feet
- Stiffness in muscles and joints, muscle spasm

Tests may show

- Fluid around the heart, gastrointestinal bleeding

Less frequent side effects

Heart and lungs

- Heart attack (including fatal outcome), 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
- 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) artery disease, inflammation of the tissue covering the heart and lungs.

Digestive problems

- Inflammation of the pancreas
- Peptic ulcer, inflammation of the food pipe
- Swollen tummy (abdomen)
- Tear in the skin of the anal canal

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 10 of 15

- 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)
- 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

Psychiatric

- Anxiety, confusion, mood swings, lower sexual drive, fainting, tremor

Skin, hair, eye, general

- Inflammation of the eye which causes redness or pain, discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- 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, increased sensitivity to light (photophobia), disturbance in skin colour
- Dizziness, spinning sensation (vertigo)
- Inflammation of fatty tissue under the skin, skin ulcer, blistering of the skin, nail disorder, hair disorder, renal failure, urinary frequency
- Breast enlargement in men, menstrual disorder, general weakness and discomfort
- Low thyroid function
- Losing balance while walking
- Convulsion(fits)
- 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 condition associated with lack of muscular coordination),

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 11 of 15

- Difficulty walking
- Miscarriage
- Inflammation of the skin blood vessels
- Skin fibrosis

Musculoskeletal and connective tissue

- Temporary paralysis or weakness of muscles(rhabdomyolysis)
- 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
- Delayed fusion of the rounded ends that form joints (epiphyses)
- Slower or delayed growth

Pain

- Inflammation of vein which can cause redness, tenderness and swelling, inflammation of the tendon

Brain

- Loss of memory
- Stroke (cerebrovascular accident), temporary episode of neurologic dysfunction caused by loss of blood flow, facial nerve paralysis, dementia

Tests may show

- Abnormal blood test results and possibly impaired kidney function caused by the waste products of the dying 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, swelling of lymph nodes in response to a bacterial or viral infection (lymphadenopathy).
- Irregularity of the electrical activity of the heart, enlarged heart

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 12 of 15

- 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)

Frequency not known

- 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)
- 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 notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of **DASAMIA**.

5. How to store DASAMIA

Store at or below 25 °C in original package

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 13 of 15

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 DASAMIA contains

The active substance is dasatinib

The other ingredients are: Lactose amonohydrate, Calcium hydrogen phosphate anhydrous, Croscarmellose sodium, Hydroxypropyl cellulose, Colloidal anhydrous silica, Magnesium stearate, Opadry White 03K580013 (Hypromellose, Titanium dioxide, Triacetin, Purified water)

What DASAMIA looks like and contents of the pack

DASAMIA 20 film coated tablets: White to off-white, biconvex, round, film-coated tablet, debossed with "851" on one side and plain on other side.

DASAMIA 50 film coated tablets: White to off-white, biconvex, oval, film-coated tablet, debossed with "852" on one side and plain on other side.

DASAMIA 70 film coated tablets: White to off-white, biconvex, round, film-coated tablet debossed with "853" on one side and plain on other side.

DASAMIA 100 film coated tablets: White to off-white, biconvex, oval, film-coated tablet, debossed with "855" on one side and plain on other side.

Contents: 30 and 60 tablets per pack

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

A Sun Pharma Company

14 Lautre Road, Stormill, Ext.1

Roodepoort, Johannesburg, 1724

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Approved PIL	Version: 0007-03/2025
Signed: 	Page 14 of 15
Approval Date: 29 May 2026	

29 May 2026

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Approved PIL	Version: 0007-03/2025
Signed:  Approval Date: 29 May 2026	Page 15 of 15