

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SUNMATIN 100 film coated tablets

SUNMATIN 400 film coated tablets

Imatinib mesilate

Contains sugar.

SUNMATIN 100: Contains 100 mg mannitol per film coated tablet.

SUNMATIN 400: Contains 400 mg mannitol per film coated tablet.

Read all of this leaflet carefully before you start taking SUNMATIN:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SUNMATIN 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 SUNMATIN is and what it is used for
2. What you need to know before you use SUNMATIN
3. How to take SUNMATIN
4. Possible side effects
5. How to store SUNMATIN
6. Contents of the pack and other information

1. What SUNMATIN is and what it is used for

SUNMATIN is a type of medication that prevents and stops the growth of some cancer cells.

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SUNMATIN is a treatment for adults and children for:

- **Chronic myeloid leukaemia (CML).** Leukaemia is a cancer of white blood cells. Treatment for adults for certain other types of leukaemia or cancer of the stomach and skin. Chronic myeloid leukaemia is a form of leukaemia in which certain abnormal white cells (named myeloid cells) start growing out of control.
- **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. SUNMATIN inhibits the growth of these cells.

SUNMATIN 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. SUNMATIN inhibits the growth of these cells in a certain subtype of these diseases.
- **Systemic mastocytosis (SM) without the D816V c-Kit mutation and eosinophilia.** This is a rare disorder that results in too many mast cells building up in your body.
- **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. SUNMATIN 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 organs.
- **Dermatofibrosarcoma protuberans (DFSP).** DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control. SUNMATIN inhibits the growth of these cells.

2. What you need to know before you take SUNMATIN

Do not take SUNMATIN:

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- If you are allergic (hypersensitive) to imatinib or to any of the other ingredients (listed in section 6).
- If you are pregnant or breastfeeding your baby (see pregnancy and breastfeeding).

Warnings and precautions:

Talk to your doctor before taking SUNMATIN:


- If you have ever had or might now have a hepatitis B infection. SUNMATIN could cause hepatitis B to become active again, which can be fatal in some cases.

Tell your doctor immediately:

- If you notice or someone notices in you: sudden numbness or weakness in the limbs (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sight loss, difficulty walking, loss of balance or lack of coordination, sudden severe headache with no known cause. These may be signs and symptoms of stroke (see possible side effects).
- If you notice bleeding at the site of the tumours or bleeding from the gastrointestinal tract (dark excretions looking like ground coffee).
- If you experience bruising, bleeding, fever, feeling tired and confusion. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).

Take special care with SUNMATIN:

- If you have a liver disease, the effects may be increased because of slower removal of imatinib from the body.
- If you are overweight.
- If you notice that you put on weight very quickly. SUNMATIN may cause your body to retain water. You should therefore be weighed regularly.
- If you are dehydrated or have gout (high uric acid levels).
- Consult your doctor if any laboratory tests have to be performed.
- If you plan to get vaccinated. Vaccination with live virus is not recommended.
- If you have a history of heart problems.

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- If you have a history of thyroid problems.
- If SUNMATIN is used in children, close monitoring of growth in children is recommended.
- You should avoid sunlight when taking SUNMATIN, as your skin or eyes can become very sensitive to sunlight or other forms of light.

Children and adolescents:

SUNMATIN 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 HES/CEL.

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

Other medicines and SUNMATIN:

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

In particular, your doctor should be informed if you are taking any of the following medicines:

- Antibiotics (such as clarithromycin, telithromycin or erythromycin), used to treat infections.
- Itraconazole, posaconazole, voriconazole or ketoconazole, used to treat fungal infections.
- Grapefruit, grapefruit juice or grapefruit-containing food or vitamins. These foods or vitamins may increase the amount of imatinib in your body and may increase the chance of side effects.
- Carbamazepine, phenobarbitone or phenytoin, used to treat epilepsy (fits/seizures).
- Dexamethasone, used to treat inflammatory and autoimmune conditions (e.g. rheumatoid arthritis).
- Rifampicin, used to treat tuberculosis (TB).
- St. John's wort, used to treat depression.
- HMG-CoA reductase inhibitors (e.g. simvastatin), used to lower cholesterol levels.
- Levothyroxine, because your thyroid has been removed.
- Ciclosporin, tacrolimus or sirolimus (immunosuppressant medicines), used after an organ

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transplant to reduce the activity of the patient's immune system and thereby the risk of organ rejection.

- Pimozide, used in schizophrenia and chronic psychosis.
- Benzodiazepines, used in treating anxiety, insomnia, agitation, seizures, muscle spasms or alcohol withdrawal.
- Calcium channel blockers, used to treat angina and high blood pressure.
- Paracetamol, used to treat pain and fever.
- Warfarin, used to prevent the forming of blood clots.
- Beta-blockers, used in the management of cardiac dysrhythmias, cardiac protection after myocardial infarction (heart attack) and high blood pressure.
- Cyclophosphamide, used to treat various types of cancer.
- Morphine and oxycodone, used to treat severe pain.
- Serotonin antagonists, used to treat psychotic disorders.
- Other bone marrow depressants or radiation therapy.
- Ergotamine, diergotamine, used to treat migraines or cluster headaches.
- Powerful opioid medicines such as fentanyl or alfentanil.
- Bortezomib, docetaxel, other type of anticancer medicines.
- Metoprolol, used to treat high blood pressure.
- Terfenadine, an antihistamine used to treat allergic conditions.

Do not have any immunisations (vaccinations) without your doctor's permission. SUNMATIN may lower your body's resistance and there is a chance you might get the infection the immunisation is meant to prevent.

SUNMATIN with food and drink:

SUNMATIN should be taken with food and a large glass of water.

If you are unable to swallow SUNMATIN, you can dissolve the tablet in a glass of still water or apple

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juice:

- Use about 50 ml if you are taking SUNMATIN 100 or use 200 ml if you are taking SUNMATIN 400.
- Stir with a spoon until the tablet has completely dissolved.
- Once the tablet has dissolved, immediately drink everything in the glass.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking SUNMATIN.

DO NOT take SUNMATIN if you are pregnant, suspect that you are pregnant or breastfeeding your baby. Contact your doctor immediately.

If you are a woman who could become pregnant you should use effective contraception during treatment with SUNMATIN and for 6 months after the last dose. If you are a male patient and your female partner could become pregnant, you should use effective contraception during treatment with SUNMATIN and for 3 months after the last dose.


Driving and using machines:

SUNMATIN may cause dizziness or blurred vision and therefore may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how SUNMATIN affects you.

3. How to take SUNMATIN

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

Always take SUNMATIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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SUNMATIN should be taken with a large glass of water and a meal (see "SUNMATIN with food and drink").

Do not take SUNMATIN with grapefruit, grapefruit juice, or grapefruit-containing foods or supplements.

The dose of SUNMATIN will be different for different patients. The dose that is used may depend on a number of things, how you are responding to the medicine and whether or not it is affecting your blood cells.

If you are taking SUNMATIN at home, follow your doctor's orders or the directions on the label. If you have any questions about the proper dose of SUNMATIN, ask your doctor.

If you take more SUNMATIN than you should:

In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take SUNMATIN:

If you miss a dose of this medicine, do not take the missed dose at all and do not take a double dose the next time. Instead, go back to your regular dosing schedule and consult your doctor.

4. Possible side effects

SUNMATIN can have side effects. Not all side effects reported for SUNMATIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SUNMATIN, please consult your doctor, pharmacist or other healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in

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swallowing or breathing.

- Rash or itching.
- Fainting.
- Nausea, vomiting, feeling tired, dark urine, numbness, fits, hallucinations, muscle cramps and heart palpitations, as it can all be symptoms of a serious life-threatening condition called tumour lysis syndrome (TLS), a condition that is caused by massive tumour cells killed and released in the bloodstream.
- A serious reaction to SUNMATIN, characterised by widespread skin rash, fever, swollen lymph nodes.

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

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

- Sudden numbness or weakness in the limbs (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sight loss, difficulty walking, loss of balance or lack of coordination, sudden severe headache (see “warnings and precautions”).
- Recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection). Symptoms may include fever, chills, weakness and vomiting.
- Yellowing of the skin and eyes, also called jaundice.
- A skin reaction causing blistering inside the mouth, nose throat, eyes and genitals.
- Thrombotic microangiopathy (a rare but serious medical disease - it is a pattern of damage that can occur in the smallest blood vessels inside many of your body’s vital organs – most commonly the kidney and brain). Symptoms may include feeling tired, fever, confusion, weakness, headache, bleeding.
- Blood in the stool, vomiting blood, general abdominal pain or discomfort.
- Subdural haematoma is a serious condition where blood collects between the skull and the surface of the brain (symptoms include headache, confusion, vomiting, slurred speech or coma).

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- Severe pelvic pain, severe nausea and vomiting, light-headedness, weakness.
- Difficulty breathing.
- Signs of recurrent infections such as fever or sore throat.
- Less urine than is normal for you.
- Swelling of your legs, ankles and feet, drowsiness or fatigue.
- Black, tarry stools.
- Bleeding problems.

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

Tell your doctor as soon as possible if you notice any of the following:

The following side effects occur frequently:

- Headache.
- Nausea, vomiting, diarrhoea, abdominal pain, heartburn, bloating, constipation.
- Muscle spasm, cramps or pain, joint pain.
- Cold and flu symptoms.
- Unusual weight loss, decreased appetite.
- Dizziness, taste disturbance, sleeplessness.
- Increased production of tears.
- Feeling cold.
- Nosebleeds, coughing, sore throat.
- Severe itching of the skin, night sweats, small red or purple spots on the body.
- Shaking occurring during a high fever, lack of energy and strength, back pain.

The following side effects occur less frequently:

- Eye irritation, eye pain, bleeding in the eye.
- Ringing in the ear, difficulty hearing.
- Dehydration (dry mouth).

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- Gout (painful swelling of ankle or foot).
- Increased or decreased appetite.
- Depression, anxiety, decreased sexual drive, confusion.
- Skin rash forming pin-head sized pustules.
- Tender bumps that are tender to touch on the legs, arms and feet.
- Breast enlargement (in men and women), nipple pain, sexual dysfunction, heavy menstrual periods in woman.
- Feeling unwell.
- Muscle weakness.
- Pain in the joint.
- Pain, weakness, numbness or tingling in the leg.


The following side effects may also occur (frequency unknown):

- 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.
- Pseudoporphyria, a condition that mimics porphyria that causes skin fragility and photosensitivity. Blisters form where the skin is exposed to the sun and are most often seen on the hands and feet.
- Slowing of growth in children and adolescents.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SUNMATIN.

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5. How to store SUNMATIN

- Store at or below 25 °C.
- Protect from light and moisture.
- Do not remove from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SUNMATIN contains:

The active ingredient is imatinib mesilate.

SUNMATIN 100: Each film coated tablet contains imatinib mesilate equivalent to 100 mg imatinib.

SUNMATIN 400: Each film coated tablet contains imatinib mesilate equivalent to 400 mg imatinib.

The other ingredients are: copovidone, crospovidone, magnesium stearate, mannitol, Opadry Yellow (containing FD&C Yellow, hypromellose, iron oxide red, iron oxide yellow, macrogol, titanium dioxide), polyethylene glycol, silicified microcrystalline cellulose.

What SUNMATIN looks like and contents of the pack:

SUNMATIN 100: Yellow coloured, round shaped, biconvex film coated tablets debossed with "472" on one side and a break line on the other side.

SUNMATIN 400: Yellow coloured, capsule shaped, biconvex film coated tablets debossed with "475" on one side and a break line on the other side.

SUNMATIN 100: Aluminium foil laminated with 150 g/m² poly layer blister strips containing 10 tablets each. Sixty (6 x 10) tablets per carton.

SUNMATIN 400: Aluminium foil laminated with 150 g/m² poly layer blister strips containing 10 tablets each. Thirty (3 x 10) tablets per carton.

Holder of certificate of registration and manufacturer:

Ranbaxy Pharmaceuticals (Pty) Ltd.

14 Lautre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

This leaflet was last revised:

04 October 2024

Registration numbers:

SUNMATIN 100: 44/26/0886

SUNMATIN 400: 44/26/0887

Date of registration:

05 December 2013

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