**Patient Information Leaflet for SUNMATIN**

# 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

Sign:

## 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.

**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:**

- 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.

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- If you plan to get vaccinated. Vaccination with live virus is not recommended.
- If you have a history of heart problems.
- 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 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.

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

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

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casualty department at your nearest hospital:

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

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- 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).
- 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.

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- Ringing in the ear, difficulty hearing.
- Dehydration (dry mouth).
- 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.

## 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/m$^2$ poly layer blister strips containing 10 tablets

each. Sixty (6 x 10) tablets per carton.

SUNMATIN 400: Aluminium foil laminated with 150 g/$m^2$ 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

Sign:

**Patient Information Leaflet for SUNMATIN**

**PASIËNTINLIGTINGSBLAD**

**SKEDULERINGSTATUS**

S4

**SUNMATIN 100** filmbedekte tablette

**SUNMATIN 400** filmbedekte tablette

**Imatinibmesilaat**

Bevat suiker.

SUNMATIN 100: Bevat 100 mg mannitol per filmbedekte tablet.

SUNMATIN 400: Bevat 400 mg mannitol per filmbedekte tablet.

**Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om SUNMATIN te neem:**

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief vir jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.
- SUNMATIN is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

**Wat is in hierdie inligtingstuk:**

1. Wat SUNMATIN is en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy SUNMATIN neem
3. Hoe om SUNMATIN te neem
4. Moontlike newe-effekte
5. Hoe om SUNMATIN te bewaar
6. Inhoud van die verpakking en ander inligting

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## 1. Wat SUNMATIN is en waarvoor dit gebruik word

SUNMATIN is ‘n soort medikasie wat die groei van sommige kankerselle voorkom en verhinder.

**SUNMATIN is ‘n hehandeling vir volwassenes en kinders vir:**

- **Chroniese miëloïed leukemie (CML).** Leukemie is ‘n kanker van witbloedselle. Behandeling by volwassenes vir sekere ander tipes leukemie of kanker van die maag en vel. Chroniese miëloïed leukemie is ‘n vorm van leukemie waarin sekere abnormale witselle (naamlik miëloïedselle) begin om buite beheer te groei.
- **Philadelphia chromosoom positiewe akute limfoblastiese leukemie (Ph-positive ALL).** Leukemie is ‘n kanker van witbloedselle. Hierdie witselle help gewoonlik die liggaam om infeksie te beveg. Akute limfoblastiese leukemie is ‘n vorm van leukemie waarin sekere abnormale witselle (naamlik limfoblaste) begin om buite beheer te groei. SUNMATIN inhibeer die groei van hierdie selle.

**SUNMATIN is ook ‘n behandeling by volwassenes vir:**

- **Miëlodisplastiese/miëloproliferatiewe siektetoestande (MDS/MPD).** Hierdie is ‘n groep bloedsiektes waarin sommige bloedselle buite beheer begin groei. SUNMATIN inhibeer die groei van hierdie selle in ‘n sekere subtipe van hierdie siektetoestande.
- **Sistemiese mastositose (SM) sonder die D816V c-Kit-mutasie en eosinofilie.** Dit is ‘n seldsame versteuring wat die resultaat het dat te veel mastselle in jou liggaam opbou.
- **Hipereosinofiliese sindroom (HES) en/of chroniese eosinofiliese leukemie (CEL).** Hierdie is bloedsiektes waarin sommige bloedselle (naamlik eosinofiele) begin om buite beheer te groei. SUNMATIN inhibeer die groei van hierdie selle in ‘n sekere subtipe van hierdie siektetoestande.
- **Gastroïntestinale stromale tumore (GIST).** GIST is ‘n kanker van die maag en derms. Dit ontstaan vanaf ongekontroleerde selgroei van die ondersteunende weefsel van hierdie organe.
- **Dermatofibrosarkoom protuberans (DFSP).** DFSP is ‘n kanker van die weefsel onder die vel waarin sommige selle begin om buite beheer te groei. SUNMATIN inhibeer die groei van hierdie

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selle.

## 2. Wat jy moet weet voordat jy begin om SUNMATIN te neem

**Moenie SUNMATIN neem nie:**

- As jy allergies (hipersensitief) is vir imatinib of vir enige van die ander bestanddele (gelys in afdeling 6).
- As jy swanger is of jou baba borsvoed (sien swangerskap en borsvoeding).

**Waarskuwings en voorsorgmaatreëls:**

Praat met jou dokter voordat jy SUNMATIN neem:

- As jy al ooit ‘n hepatitis-B-infeksie gehad het of nou mag hê. SUNMATIN kan veroorsaak dat hepatitis-B weer aktief raak, wat fataal in sommige gevalle kan wees.

Lig jou dokter dadelik in:

- As jy of iemand anders die volgende by jou opmerk: skielike doodse gevoel of swakheid van die ledemate (veral aan die een kant van die liggaam), skielike verwarring, moeilike spraak of om ‘n gesprek te verstaan, verlies aan sig, sukkel om te stap, verlies aan balans of verlies van koördinasie, skielike erge hoofpyn met geen bekende oorsaak. Hierdie kan tekens en simptome van beroerte wees (sien moontlike newe-effekte).
- As jy bloeding by die ligging van die tumore of bloeding van die gastroïntestinale baan opmerk (donker afskeidings wat lyk soos gemaalde koffie).
- As jy kneusing, bloeding, koors, ‘n moeë gevoel en verwarring ervaar. Dit mag ‘n teken van skade aan jou bloedvate wees wat bekend staan as trombotiese mikro-angiopatie (TMA).

Tref spesiale voorsorg met SUNMATIN:

- As jy ‘n lewersiekte het, kan die effekte verhoog wees omdat daar ‘n stadiger opruiming van imatinib uit die liggaam is.
- As jy oorgewig is.

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- As jy opmerk dat jy baie vinnig gewig aangesit het. SUNMATIN kan veroorsaak dat jou liggaam vog terughou. Jy moet daarom gereeld geweeg word.
- As jy gedehidreer is of jig het (hoë uriensuurvlakke).
- Raadpleeg jou dokter as enige laboratoriumtoetse uitgevoer moet word.
- As jy beplan om ingeënt te word. Inenting met lewendige virus word nie aanbeveel nie.
- As jy ‘n geskiedenis van hartprobleme het.
- As jy ‘n geskiedenis van skildklierprobleme het.
- Indien SUNMATIN by kinders gebruik word, word noukeurige monitoring van die groei in kinders aanbeveel.
- Jy moet sonlig vermy wanneer jy SUNMATIN neem, aangesien jou vel of oë baie sensitief vir sonlig of ander vorme van lig kan raak.

**Kinders en adolessente :**

SUNMATIN is ook ‘n behandeling by kinders met CML. Daar is geen ervaring by kinders met CML onder die ouderdom van 2 jaar nie. Daar is beperkte ervaring by kinders met Ph-positiewe ALL en baie beperkte ervaring by kinders met MDS/MPD, DFSP, GIST en HES/CEL.
Sommige kinders en adolessente wat SUNMATIN neem, kan ‘n stadiger groei as normaalweg hê. Die dokter sal die groei monitor tydens gereelde besoeke.

**Ander medisyne en SUNMATIN:**

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in).
Jou dokter moet veral ingelig word as jy enige van die volgende medisyne gebruik:

- Antibiotika (soos klaritromisien, telitromisien of eritromisien), gebruik om infeksie te behandel.
- Itrakonasool, posakonasool, vorikonasool of ketokonasool, gebruik om swaminfeksie te behandel.
- Pomelo’s, pomelosap of pomelobevattende voedsel of vitamiene. Hierdie voedselsoorte of

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viatamiene kan die hoeveelheid imatinib in jou liggaam verhoog en kan die moontlikheid om newe-effekte te ervaar, verhoog.

- Karbamasepien, fenobarbitoon of fenitoïen, wat gebruik word om epilepsie (aanvalle/toevalle) te behandel.
- Deksametasoon, gebruik om inflammatoriese en outoimmuuntoestande te behandel (bv. rumatoïede artritis).
- Rifampisien, gebruik om tuberkulose te behandel (TB).
- Johanneskruid, gebruik om depressie te behandel.
- HMG-KoA-reduktase-inhibeerders (bv. simvastatien), gebruik om cholesterolvlakke te verlaag
- Levotiroksien, omdat jou skildklier verwyder is.
- Siklosporien, takrolimus of sirolimus (medisyne vir immuunonderdrukking), gebruik ná orgaanoorplanting om die aktiwiteit van die pasiënt se immuunstelsel te verlaag en daardeur die risiko van verwerping ná orgaanoorplanting.
- Pimosied, gebruik by skisofrenie en chroniese psigose.
- Bensodiasepiene, gebruik in die behandeling van angstigheid, slapeloosheid, agitasie, toevalle, spierspasma of alkoholonttrekking.
- Kalsiumkanaalblokkeerders, gebruik om angina en hoë bloeddruk te behandel.
- Parasetamol, gebruik om pyn en koors te behandel.
- Warfarien, gebruik om die vorming van bloedklonte te voorkom.
- Beta-blokkeerders, gebruik in die beheer van hartdisritmie, kardiale beskerming ná miokardiale infarksie (hartaanval) en hoë bloeddruk.
- Siklofosfamied, gebruik om verskeie tipes kanker te behandel.
- Morfien en oksikodoon, gebruik om erge pyn te behandel.
- Serotonienantagoniste, gebruik om psigotiese versteurings te behandel.
- Ander beenmurgonderdrukkers of bestralingsterapie.
- Ergotamien, di-ergotamien, gebruik om migraine of troshoofpyn te behandel.
- Kragtige opioïed-medisyne soos fentaniel of alfentaniel.

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- Bortezomib, dosetaksel, ander tipe antikanker medisyne.
- Metoprolol, gebruik om hoë bloeddruk te behandel.
- Terfenadien, ‘n antihistamien gebruik om allergiese toestande te behandel.

Moenie immunisasies (inentings) sonder jou dokter se toestemming kry nie. SUNMATIN kan jou liggaam se weerstand verlaag en daar is ‘n moontlikheid dat jy die infeksie kan opdoen waarvoor die immunisasie bedoel was om dit te voorkom.

**SUNMATIN saam met voedsel en drinkgoed:**

SUNMATIN moet saam met voedsel en ‘n groot glas water geneem word.

As jy nie in staat is om SUNMATIN te sluk nie, kan jy die tablet oplos in ‘n glas water of appelsap:

- Gebruik ongeveer 50 mL as jy SUNMATIN 100 neem of gebruik 200 mL as jy SUNMATIN 400 neem.
- Roer met ‘n lepel totdat die tablet heeltemal opgelos het.
- Sodra die tablet opgelos het, moet jy dadelik alles in die glas drink.

**Swangerskap, borsvoeding en vrugbaarheid:**

As jy swanger is of jou baba borsvoed, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg vir advies voordat jy SUNMATIN neem.

MOENIE SUNMATIN neem as jy swanger is, vermoed dat jy swanger mag wees of as jy jou baba borsvoed nie. Jou dokter moet onmiddellik geraadpleeg word.

As jy ‘n vrou is wat swanger kan raak terwyl jy met SUNMATIN behandel word en vir 6 maande ná die laaste dosis, moet jy doeltreffende voorbehoeding gebruik. As jy ‘n manlike pasiënt is en jou

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vroulike maat swanger kan raak, moet jy doeltreffende voorbehoeding tydens behandeling met SUNMATIN gebruik en vir 3 maande ná die laaste dosis.

**Bestuur en gebruik van masjinerie:**

SUNMATIN kan duiseligheid of belemmerde visie veroorsaak en daarom jou vermoë om te bestuur en masjinerie te hanteer, benadeel. Moenie bestuur, masjinerie hanteer of enigiets anders doen wat gevaarlik kan wees nie totdat jy weet hoe SUNMATIN jou affekteer.

## 3. Hoe om SUNMATIN te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem SUNMATIN altyd presies soos wat jou dokter dit voorgeskryf het. Jy moet met jou dokter of apteker kontroleer as jy onseker is.

SUNMATIN moet met ‘n groot glas water en ‘n maaltyd geneem word (sien “SUNMATIN saam met voedsel en drinkgoed”).
Moenie SUNMATIN saam met pomelo’s, pomelosap, of pomelo-bevattende voedsel of aanvullings neem nie.

Die dosis van SUNMATIN sal verskillend wees vir verskillende pasiënte. Die dosis wat gebruik word, hang van ‘n aantal dinge af; hoe jy op die medisyne reageer en of dit jou selle affekteer of nie.
Indien jy SUNMATIN by die huis neem, volg die dokter se voorskrif of die aanwysings op die etiket.
Vra jou dokter as jy enige vrae het oor die behoorlike dosis van SUNMATIN.

**As jy meer SUNMATIN geneem het as wat jy behoort te neem:**

In geval van per ongeluk of opsetlike oordosis, kontak jou dokter of apteker so gou as moontlik.
Indien nie een van hulle beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.
Neem hierdie inligtingstuk en enige oorblywende tablette saam met jou sodat die dokter kan weet

Sign:

wat jy geneem het.

**As jy vergeet het om SUNMATIN te neem:**

As jy ‘n dosis van hierdie medisyne oorgeslaan het, moet jy gladnie die oorgeslaande dosis neem nie en moenie die volgende keer ‘n dubbele dosis neem nie. In plaas daarvan, moet jy teruggaan na jou normale dosisskedule en jou dokter raadpleeg.

## 4. Moontlike newe-effekte

SUNMATIN kan newe-effekte hê. Nie alle newe-effekte wat vir SUNMATIN aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou versleg of as jy enige ongewenste effekte ervaar terwyl jy SUNMATIN neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies.

Indien enige van die volgende gebeur, staak die gebruik van SUNMATIN en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- Swelling van die hands, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak.
- Uitslag of gejeuk.
- Floute.
- Naarheid, braking, moeë gevoel, donker urine, doodse gevoel, toevalle, hallusinasies, spierkarampe en hartpalpitasies, aangesien dit alles simptome van ‘n ernstige lewensbedreigende toestand kan wees wat bekend staan as tumorlise-sindroom (TLS), ‘n toestand wat veroorsaak word deur die doodmaak van massiewe hoeveelhede tumorselle wat in die bloedstroom vrygestel word.
- ‘n Ernstige reaksie teenoor SUNMATIN, gekenmerk deur wydverspreide veluitslag, koors, geswelde limfkliere.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige allergiese reaksie teenoor

SUNMATIN gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Skielike doodse gevoel of swakheid in die ledemate (veral aan die een kant van die liggaam), skielike verwarring, sukkel om te praat of ‘n gesprek te volg, gesigsverlies, moeilike stap, verlies aan balans of verlies aan koördinasie, skielike erge hoofpyn (sien “waarskuwings en voorsorgmaatreëls”).
- Herhaling (heraktivering) van hepatitis-B-infeksie as jy reeds hepatitis-B in die verlede gehad het (‘n infeksie van die lewer). Simptome kan koors, koue koors, swakheid en braking insluit.
- Vergeling van die vel en oë, ook geelsug genoem.
- ‘n Velreaksie wat blasievorming binne-in die mond, neus, keel, oë en geslagsdele veroorsaak.
- Trombotiese mikro-angiopatie (‘n seldsame maar ernstige mediese siektetoestand – dit is ‘n patroon van skade wat in die kleinste bloedvate binne-in baie van jou liggaam se lewensbelangrike organe kan voorkom – mees algemeen die nier en brein). Simptome kan moeë gevoel, koors, verwarring, swakheid, hoofpyn en bloeding insluit.
- Bloed in die stoelgang, gooi bloed op, algemene buikpyn of ongemak.
- Subdurale hematoom is ‘n ernstige toestand waar bloed versamel tussen die kopbeen en die oppervlak van die brein (simptome sluit hoofpyn, verwarring, braking, sleepspraak of koma in).
- Ernstige pelviese pyn, ernstige naarheid en braking, lighoofdigheid, swakheid.
- Moeilike asemhaling.
- Tekens van herhalende infeksie soos koors en seerkeel.
- Minder urine as wat normaal is vir jou.
- Swelling van jou bene, enkels en voete, lomerigheid of moegheid.
- Swart, teeragtige stoelgange.
- Bloedingsprobleme.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese bystand benodig.

Sign:

Lig jou dokter so gou as moontlik in as jy enige van die volgende opmerk:

Die volgende newe-effekte kom dikwels voor:

- Hoofpyn.
- Naarheid, braking, diaree, maagpyn, sooibrand, opgeblasenheid, hardlywigheid.
- Spierspasma, krampe of pyn, gewrigspyn.
- Verkoue en griepsimptome.
- Ongewone gewigsverlies, afname in eetlus.
- Duiseligheid, smaakversteuring, slapeloosheid.
- Verhoogde traanproduksie.
- Voel koud.
- Neusbloedings, hoes, seerkeel.
- Erge gejeuk van die vel, nagsweet, klein rooi of pers kolletjies op die liggaam.
- Bewerigheid wat voorkom tydens ‘n hoë koors, gebrek aan energie en krag, rugpyn.

Die volgende newe-effekte kom minder dikwels voor:

- Oogirritasie, oogpyn, bloeding in die oog.
- Suising in die oor, sukkel om te hoor.
- Dehidrasie (droë mond).
- Jig (pynlike swelling van die enkel of voet).
- Verhoogde of verlaagde eetlus.
- Depressie, angstigheid, verlaagde seksdrang, verwarring.
- Veluitslag wat speldepunt grootte sweertjies vorm.
- Teer knoppe, wat teer is met aanraking, op die bene, arms en voete.
- Borsvergroting (by mans en vroue), pyn in die tepel, seksuele wanfunksie, swaar menstruasieperiodes by vroue.
- Onwelgevoel.

Sign:

- Spierswakheid.
- Pyn in die gewrigte.
- Pyn, swakheid, doodse gevoel of tinteling in die been.

Die volgende newe-effekte kan ook voorkom (voorkoms onbekend):

- Rooi word en/of swelling van die handpalms en voetsole wat gepaard kan gaan met ‘n tintelende sensasie en brandende pyn.
- Pseudoporfirie, ‘n toestand wat porfirie naboots wat velteerheid en fotosensitiwiteit veroorsaak. Blase vorm waar die vel aan sonlig blootgestel word en word meestal op die hande en voete waargeneem.
- Vertraging van groei by kinders en adolessente.

Jy moet jou dokter of apteker inlig as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

**Aanmelding van newe-effekte:**

Praat met jou dokter of apteker as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die Med Safety APP (Medsafety X SAHPRA) en eReporting-platform (who-umc.org) wat aanlyn beskikbaar is op SAHPRA se webblad. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van SUNMATIN te verskaf.

## 5. Hoe om SUNMATIN te bewaar

- Bewaar by of onder 25 °C.
- Beskerm teen li gen vog.
- Moenie uit die buitenste karton verwyder tot benodig vir gebruik nie.
- **BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.**
- Moenie ná die vervaldatum soos op die etiket en karton gedruk, gebruik nie.
- Bring alle ongebruikte medisyne terug na jou apteker toe.

Sign:

- Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

## 6. Inhoud van die verpakking en ander inligting

**Wat SUNMATIN bevat:**

Die aktiewe bestanddeel is imatinibmesilaat.

SUNMATIN 100: Elke filmbedekte tablet bevat imatinibmesilaat gelykstaande aan 100 mg imatinib.

SUNMATIN 400: Elke filmbedekte tablet bevat imatinibmesilaat gelykstaande aan 400 mg imatinib.

Die ander bestanddele is: kopovidoon, krospovidoon, magnesiumstearaat, mannitol, Opadry Geel (bevattende FD&C geel, hipromellose, rooi ysteroksied, geel ysteroksied, makrogol, titaandioksied), poliëtileenglikool, silisifiseerde mikrokristallyne sellulose.

**Hoe SUNMATIN lyk en inhoud van die verpakking:**

SUNMATIN 100: Geelkleurige, ronde, bikonvekse filmbedekte tablette ingepers met “472” op die een kant en ‘n breeklyn op die ander kant.

SUNMATIN 400: Geelkleurige, kapsule-vormige, bikonvekse filmbedekte tablette ingepers met “475” op die een kant en ‘n breeklyn op die ander kant.

SUNMATIN 100: Aluminiumfoelie gelamineer met 150 g/m$^2$ polilagige stulpstroke wat elke 10 tablette bevat. Sestig (6 x 10) tablette per karton.

SUNMATIN 400: Aluminiumfoelie gelamineer met 150 g/m$^2$ polilagige stulpstroke wat elke 10 tablette bevat. Dertig (3 x 10) tablette per karton.

**Houer van die registrasiesertifikaat en vervaardiger:**

Ranbaxy Pharmaceuticals (Pty) Ltd.

Lautreweg 14, Stormill, Uitbreiding1,

Roodepoort, 1724

Sign:

Suid-Afrika

**Hierdie inligtingstuk was laas hersien op:**

04 Oktober 2024

**Registrasienommers:**

SUNMATIN 100: 44/26/0886

SUNMATIN 400: 44/26/0887

**Datum van registrasie:**

05 Desember 2013

Sign: