

SCSEMBLIX®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking Scemblix?

Scemblix contains the active ingredient asciminib. Scemblix is used to treat patients 18 years and over with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) and patients with Ph+ CML in CP who have a certain genetic difference (mutation) called T315I.

For more information, see Section [1. Why am I taking Scemblix?](#) in the full CMI.

2. What should I know before I take Scemblix?

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Scemblix?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Scemblix and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Scemblix?

- The usual total daily dose of Scemblix is 80 mg (2 tablets of Scemblix 40 mg, per day). Do not take Scemblix with food.

More instructions can be found in Section [4. How do I take Scemblix?](#) in the full CMI.

5. What should I know while taking Scemblix?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Scemblix.• Have regular tests to monitor your condition |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take Scemblix with food |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Scemblix affects you. |
| Drinking alcohol | <ul style="list-style-type: none">• There are no known interactions between Scemblix and alcohol. |
| Looking after your medicine | <ul style="list-style-type: none">• Store below 25°C (blister) or 30°C (bottle); protect from moisture |

For more information, see Section [5. What should I know while taking Scemblix?](#) in the full CMI.

6. Are there any side effects?

Common side effects include sudden bleeding or bruising; fever, sore throat, frequent infections; nose and throat infections; tiredness, pale skin; headache, dizziness, chest pain or difficulty breathing; cough; vomiting; diarrhoea; feeling sick; stomach pain; rash; pain in muscles, bones or joints; joint pain; itching.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Scemblix®

Active ingredient(s): *asciminib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Scemblix. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Scemblix.**

Where to find information in this leaflet:

- [1. Why am I taking Scemblix?](#)
- [2. What should I know before I take Scemblix?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Scemblix?](#)
- [5. What should I know while taking Scemblix?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Scemblix?

Scemblix contains the active ingredient asciminib.

Scemblix treats a type of blood cancer (leukaemia) in which the body produces too many abnormal white blood cells. Chronic phase (CP) is the first phase of this blood cancer.

Scemblix is used to treat patients 18 years and over with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in CP who

- were previously treated with 2 or more medicines of a similar type called tyrosine kinase inhibitors.
- are newly diagnosed and have received no previous treatment.
- have a certain genetic difference (mutation) called T315I.

Scemblix blocks the action of a protein (BCR-ABL1) of the abnormal white blood cells and stops them expanding and growing.

2. What should I know before take Scemblix?

Warnings

Do not take Scemblix if:

- you are allergic to asciminib, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have or have ever had severe upper stomach pain (inflamed pancreas, pancreatitis).
- have or have ever had a hepatitis B infection. This is because during treatment with Scemblix, hepatitis B may become active again. Patients will be carefully checked by their doctor for signs of this infection before starting treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss with you the potential risks of taking Scemblix during pregnancy or breast-feeding.

It is not known if Scemblix passes into your breast-milk. Breast-feeding is not recommended during treatment with Scemblix and for at least 3 days after the last dose.

Females of child-bearing potential

Scemblix can harm your unborn baby. If you are a woman of child-bearing age, your doctor, pharmacist or healthcare provider will check if you are pregnant and perform a pregnancy test if necessary before starting treatment with Scemblix.

- If you may become pregnant, you should use an effective birth control during treatment with Scemblix and for at least 3 days after the last dose. Ask your doctor about effective birth control options.

Children and adolescents

- Scemblix is not to be used in children or adolescents under 18 years of age. It is not known whether Scemblix is safe and effective in children or adolescents.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Scemblix and affect how it works:

- Medicines used to treat bacterial infections such as clarithromycin, telithromycin or troleandomycin.
- Medicines used to treat fungal infections such as itraconazole, ketoconazole or voriconazole.
- Medicines used to treat human immunodeficiency virus (HIV) such as ritonavir, indinavir, nelfinavir or saquinavir.
- An antibiotic used to treat infections caused by bacteria (rifampicin).
- Medicines used to treat seizures such as carbamazepine, phenobarbital or phenytoin.
- St. John's wort (also known as *Hypericum perforatum*), a herbal medicine used to treat depression and other conditions.

Food also interferes with Scemblix and affects how it works. Therefore do not take Scemblix with food.

Scemblix may interfere with some medicines and affect how they work:

- Medicines used to treat pain or used as sedatives before or during medical or surgical procedures, such as alfentanil, fentanyl or midazolam.
- Medicines used to treat migraine or dementia, such as dihydroergotamine or ergotamine.
- Medicines used to reduce the blood's ability to clot, such as warfarin.
- Medicines used to treat severe inflammation of the bowel or severe rheumatic joint inflammation, such as sulfasalazine.
- Medicines used to treat cancer, severe rheumatic joint inflammation, or psoriasis, such as methotrexate
- Medicines used to reduce blood cholesterol levels, such as pravastatin, atorvastatin, rosuvastatin and simvastatin

Caution should be used when taking Scemblix with medicines that may have an unwanted effect on the electrical activities of the heart (torsades de pointes), such as bepridil, chloroquine, clarithromycin, halofantrine, haloperidol, methadone, moxifloxacin or pimozone.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Scemblix.

4. How do I take Scemblix?

How much to take

- Take Scemblix exactly as your doctor tells you

- Do not change your dose or how frequently you take Scemblix or stop taking Scemblix unless your doctor tells you to.

When to take Scemblix

- If instructed to take daily dose once a day take dose at the same time each day.
- If instructed to take dose twice a day, take each dose at the same times each day, approximately 12 hours apart.

How to take Scemblix

- Take Scemblix without food. You should avoid eating for at least 2 hours before and 1 hour after taking Scemblix.
- Swallow tablets whole. Do not break, crush or chew Scemblix tablets.

If you forget to use Scemblix

Scemblix should be used regularly at approximately the same time each day.

If you take Scemblix once daily:

If you miss your dose at the usual time by more than 12 hours, skip the missed dose and take the next one as usual.

If you take Scemblix twice daily:

If you miss your dose at the usual time by more than 6 hours, skip the missed dose and take the next one as usual.

If you take too much Scemblix

If you think that you have taken too much Scemblix, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Scemblix?

Things you should do

- Keep all doctor's appointments, as your doctor needs to regularly monitor your condition.

Call your doctor straight away if you:

- experience rash, itching, hives, difficulty breathing, wheezing or coughing, light-headedness, dizziness,

skin reddening, face/throat swelling, blue discoloration of the lips, tongue or skin (signs of allergic reaction).

Remind any doctor, dentist or pharmacist you visit that you are using Scemblix.

Things you should not do

- Do not stop taking this medicine suddenly.

Monitoring during your treatment

You will have regular tests including blood tests during treatment. These tests will monitor:

- The amount of blood cells (white blood cells, red blood cells and platelets).
- The levels of pancreas enzymes (amylase and lipase).
- The levels of electrolytes (potassium, magnesium).
- Your heart rate (this could include an electrocardiogram/ECG) and your blood pressure.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Scemblix affects you.

If you experience dizziness or changes to your vision (such as blurred vision), you should not take part in these activities.

Drinking alcohol

Tell your doctor if you drink alcohol.

There are no known interactions between Scemblix and alcohol.

Looking after your medicine

- Store below 25°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|--|
| <p>Respiratory such as:</p> <ul style="list-style-type: none">• Nose, throat or sinus infections• Cough <p>Stomach side effects such as:</p> <ul style="list-style-type: none">• Diarrhoea• Vomiting• Feeling sick, nausea• Stomach pain• Constipation <p>Hormone problems:</p> <ul style="list-style-type: none">• Tiredness, weight gain, skin and hair changes (underactive thyroid gland) <p>General such as:</p> <ul style="list-style-type: none">• Tiredness, pale skin• Headache• Dizziness• Rash• Pain in muscles, bones or joints | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.</p> |

| Less serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● Itching ● Loss of appetite ● Blurred vision ● Dry eyes ● Generalised swelling ● Tiredness, weight gain and hair changes (underactive thyroid gland) | |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> ● Signs of an allergic reaction including trouble breathing or swallowing; swelling of the face, lips or tongue; skin rash or flushing of your skin; feeling dizzy or faint; fever; fast heartbeat ● Fever, coughing, difficulty breathing, wheezing (signs of lower respiratory tract infections) | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● Chest pain or difficulty breathing/shortness of breath, irregular heartbeat, swelling in the ankles or feet, dizziness, weight gain, numbness or weakness on one side of your body, decreased vision/loss of vision, trouble talking, pain in your arms, legs, back, neck or jaw, headache, severe stomach area pain. This could be related to heart problems. ● Sudden bleeding or bruising, blood in your urine or stool, fever, or any signs of infection. This could be related to low blood counts. ● Fever, sore throat, frequent infections ● Influenza ● Fever above 38°C ● Severe upper stomach pain | |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● Sudden stomach-area pain or discomfort, nausea or vomiting. This could be related to pancreas problems. ● Symptoms of elevated blood pressure including confusion, headaches, dizziness, chest pain or shortness of breath. | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Scemblix contains

| | |
|---|---|
| Active ingredient (main ingredient) | asciminib |
| Other ingredients (inactive ingredients) | Lactose monohydrate, microcrystalline cellulose, hypromellose, croscarmellose sodium, polyvinyl alcohol, titanium dioxide, magnesium stearate, purified talc, silicon dioxide, iron oxide (20 mg: yellow and red; 40 mg & 100 mg: black and red), lecithin, xanthan gum |
| Potential allergens | Sugars as lactose and soybean products |

Do not take this medicine if you are allergic to any of these ingredients.

What Scemblix looks like

Scemblix is supplied as:

Scemblix 20 mg film coated tablets: The tablets are pale yellow, round, biconvex, film-coated tablets with beveled edges, approximately 6.2 mm diameter, unscored, debossed with “Novartis” logo on one side and “20” on the other side. in Scemblix 20 mg film coated tablets in blister packs containing 20 or 60 tablets (Aust R 371019).

Scemblix 20 mg film coated tablets in bottles containing 20 or 60 tablets (AUST R 407914).*

Scemblix 40 mg film coated tablets: The tablets are violet white, round, biconvex, film-coated tablets with beveled edges, approximately 8.2 mm diameter, unscored, debossed with "Novartis" logo on one side and “40” on the other side. in Scemblix 40 mg film coated tablets in blister packs containing blister packs containing 20 or 60 tablets (Aust R 371018).

Scemblix 40 mg film coated tablets in bottles containing 20, 60 or 300 tablets (AUST R 407913).*

Scemblix 100 mg film coated tablets: The tablets are light red, unscored, round, biconvex film-coated tablet with beveled edges, approximately 11.2 mm diameter, debossed with “100” on one side and "Novartis logo" on the other side. Scemblix 100 mg film coated tablets in bottles containing 28 or 60 tablets (AUST R 466033).*

*Not all products may be marketed

Who distributes Scemblix

Scemblix is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

(ABN 18 004 244 160)

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Website: www.novartis.com.au

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