



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®

asciminib

Consumer Medicine Information

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

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 medicines of a similar

type called tyrosine kinase inhibitors.

- 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.

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.