

SCSEMBLIX[®] FILM-COATED TABLETS

Asciminib (20mg, 40mg)

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What Scemblix is used for

Scemblix is a cancer medicine used to treat adults with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP).

It is also used to treat adults with Ph+ CML-CP who have a certain genetic difference (mutation) called T315I.

How Scemblix works

In Ph+ CML, the body produces large numbers of abnormal white blood cells. Scemblix blocks the action of a protein (BCR:ABL1) that is produced by these abnormal white blood cells and stops their division and growth.

If you have any questions about how this medicine works or why this medicine has been prescribed for you, ask your doctor or pharmacist.

Before you use Scemblix

• When you must not use it

Do not take Scemblix if you are allergic to asciminib or any of the other ingredients of this medicine. Always check the ingredients to make sure you can use this medicine.

Children and adolescents

It is not known if Scemblix is safe and effective in children.

Pregnancy and breastfeeding

Talk to your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Scemblix.

Tell your healthcare provider if you are breastfeeding or plan to breastfeed.

It is not known if Scemblix passes into breast milk. Do not breastfeed during treatment and for 1 week after the last dose of Scemblix.

Females of childbearing potential

Your healthcare provider will do a pregnancy test before you start treatment with Scemblix.

You should use an effective birth control (contraception) during treatment with Scemblix and for 1 week after your last dose of Scemblix. Talk to your healthcare provider about birth control methods that may be right for you.

• Before you start use it

Tell your healthcare provider about all your medical conditions, including if you:

- Have a history of inflammation of your pancreas (pancreatitis)
- Have a history of heart problems or blood clots in your arteries and veins (type of blood vessels)
- Are pregnant or plan to become pregnant. Scemblix can harm your unborn baby.

• Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and over-the counter medicines, vitamins and herbal supplements.

Taking Scemblix with certain medicines may affect each other causing side effects and may affect the way Scemblix works.

How to use Scemblix

• How much to use

- Take Scemblix exactly as your healthcare provider tells you.
- Do not change your dose or schedule or stop taking Scemblix unless your healthcare provider tells you to.

• 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.

• When to use it

- 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 long to use it

Use this medicine for the duration that your doctor recommends.

• If you forget to use it

If you take Scemblix 1 time a day and miss a dose by more than 12 hours, skip the missed dose and take your next dose at your regular time.

If you take Scemblix 2 times a day and miss a dose by more than 6 hours, skip the missed dose and take your next dose at your regular time.

• If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

• Things you must do

Talk to your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Scemblix.

• Things you must not do

Do not stop taking this medicine suddenly.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Scemblix for a condition for which it was not prescribed. Do not give Scemblix to other people, even if they have the same symptoms you have. It may harm them.

• Things to be careful of

Driving and 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.

Side effects

Scemblix may cause serious side effects, including:

- **Low blood cell counts.** Scemblix may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your healthcare provider will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with Scemblix. Tell your healthcare provider right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection.
- **Pancreas problems.** Scemblix may increase enzymes in your blood called amylase and lipase, which may be a sign of inflammation of the pancreas (pancreatitis). Your healthcare provider may do blood tests monthly or as needed during treatment with Scemblix to check for problems with your pancreas. Tell your healthcare provider right away if you have severe stomach-area (abdominal) pain or discomfort, nausea, or vomiting.
- **High blood pressure.** Your healthcare provider may check your blood pressure and treat any high blood pressure during treatment with Scemblix as needed. Tell your healthcare provider if you develop high blood pressure or symptoms of high blood pressure, including confusion, headaches, dizziness, chest pain, or shortness of breath.
- **Allergic reaction.** Stop taking Scemblix and get medical help right away if you get any signs or symptoms 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

- **Heart and blood vessel (cardiovascular) problems.** Scemblix may cause heart and blood vessel problems, including heart attack, stroke, blood clots or blockage of your arteries, heart failure, and abnormal heartbeat, which can be serious and may sometimes lead to death. In the majority of cases, these heart and blood vessel problems happened in people with risk factors or a history of these problems, and previously treated with other tyrosine kinase inhibitor (TKI) medicines. Your healthcare provider may monitor you for heart and blood vessel problems and treat you as needed during treatment with Scemblix. Tell your healthcare provider or get medical help right away if you get:

- Shortness of breath
- Chest pain or pressure
- Feeling like your heart is beating too fast or you feel abnormal heartbeats
- Swelling in your ankles or feet
- Dizziness
- Weight gain
- Numbness or weakness on one side of your body
- Decreased vision or loss vision
- Trouble talking
- Pain in your arms, legs, back, neck or jaw
- Headache
- Severe stomach-area (abdominal) pain

The most common side effects of Scemblix include:

- Muscle, bone or joint pain
- Rash
- Tiredness
- Nose, throat, or sinus (upper respiratory tract) infections
- Headache
- Stomach-area (abdominal) pain
- Diarrhea
- Decreased white blood cell counts, platelet counts and red blood cell counts
- Decreased blood calcium corrected levels
- Increased blood pancreas enzyme (lipase and amylase) levels
- Increased blood fat (cholesterol and triglycerides)
- Increased blood uric acid levels
- Increased blood liver enzyme levels

- Increased blood alkaline phosphatase levels
- Increased blood creatine kinase levels

Your healthcare provider may change your dose or temporarily or permanently stop treatment with Scemblix if you have certain side effects.

Scemblix may cause fertility problems in females. This may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you. These are not all of the possible side effects of Scemblix.

Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ScemblixStorage

- Keep out of the reach and sight of children.
- Do not take this medicine after the expiry date, which is stated on the box.
- Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the dessicant. Discard 1 month after opening.
- Store below 30 °C.
- Do not use this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Disposal

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 to protect the environment.

Product DescriptionWhat it looks like

Scemblix 20 mg film-coated tablets (tablets): pale yellow, unscored, round, biconvex tablet with bevelled edges of approximately 6.2 mm diameter, debossed with “Novartis” logo on one side and “20” on the other side.

Scemblix 40 mg film-coated tablets (tablets): violet white, unscored, round, biconvex tablet with bevelled edges of approximately 8.2 mm diameter, debossed with “Novartis” logo on one side and “40” on the other side.

Packaging

Scemblix is supplied in HDPE bottles with dessicant containing 60 film-coated tablets.

Ingredients

- Active ingredient
 - Each 20 mg film-coated tablet contains asciminib hydrochloride, equivalent to 20 mg asciminib.
 - Each 40 mg film-coated tablet contains asciminib hydrochloride, equivalent to 40 mg asciminib.
- Inactive ingredients
 - 20 mg and 40 mg film-coated tablets: lactose monohydrate, microcrystalline cellulose (E460i), hydroxypropylcellulose (E463), croscarmellose sodium (E468), polyvinyl alcohol (E1203), titanium dioxide (E171), magnesium stearate, talc (E553b), colloidal silicon dioxide, lecithin (E322), xanthan gum (E415), iron oxide red (E172).
 - 20 mg film-coated tablets only: iron oxide yellow (E172)
 - 40 mg film-coated tablets only: iron oxide black (E172).

MAL number(s):

Scemblix 20 mg film-coated tablet:

MAL23056001ARZ

Scemblix 40 mg film-coated tablet:

MAL23056002ARZ

Manufacturer

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Slovenia

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Information Issued

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Product Registration Holder