**Package leaflet: Information for the patient**

**Scemblix® 20 mg film-coated tablets**
**Scemblix® 40 mg film-coated tablets**
asciminib

▼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. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Scemblix is and what it is used for
2. What you need to know before you take Scemblix
3. How to take Scemblix
4. Possible side effects
5. How to store Scemblix
6. Contents of the pack and other information


## 1. What Scemblix is and what it is used for

**What Scemblix is**
Scemblix contains the active substance asciminib, which belongs to a group of medicines called protein kinase inhibitors.

**What Scemblix is used for**
Scemblix is used to treat adults with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (Ph+ CML-CP) that do not have a genetic difference (mutation) called T315I and who were previously treated with at least two medicines called tyrosine kinase inhibitors.

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

**How Scemblix works**
Scemblix blocks the action of a protein (BCR-ABL1) produced by the abnormal white blood cells and stops their division and growth.

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

## 2. What you need to know before you take Scemblix

**Do not take Scemblix**
- if you are allergic to asciminib or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Scemblix if any of the following applies to you:
- if you have or have ever had pancreatitis (inflamed pancreas that is associated with severe upper stomach pain that may radiate to the back ).
- if you have ever had or might now have a hepatitis B infection. This is because Scemblix could cause hepatitis B to become active again. You will be carefully checked by your doctor for signs of this infection before treatment is started.

**Tell your doctor or pharmacist immediately if you get any of the following during treatment with Scemblix:**
- if you experience weakness, spontaneous bleeding or bruising and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of decreased bone marrow activity, resulting in a reduced number of white blood cells, red blood cells and platelets, also known as myelosuppression).
- if blood tests show that you have high levels of enzymes called lipase and amylase (signs of damage to the pancreas, also known as pancreatic toxicity).
- if you have a heart disorder or a heart rhythm disorder, such as an irregular heartbeat or an abnormal electrical signal called prolongation of the QT interval.
- if blood tests show that you have a low level of potassium or magnesium (hypokalaemia or hypomagnesaemia).
- if you are being treated with medicines that may have an unwanted effect on the function of the heart (torsades de pointes) (see "Other medicines and Scemblix")
- if you experience headache, dizziness, chest pain or shortness of breath (signs of high blood pressure, also known as hypertension).

**Monitoring during your treatment with Scemblix**
Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. 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 and blood pressure.

**Children and adolescents**
Do not give this medicine to children or adolescents aged under 18 years. No data are available in this age group.

**Other medicines and Scemblix**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are using:
- medicines used to treat seizures (fits), such as carbamazepine, phenobarbital or phenytoin.
- medicines used to treat pain and or as sedatives before or during medical or surgical procedures, such as alfentanil or fentanyl.
- medicines used to treat migraine or dementia, such as dihydroergotamine or ergotamine.
- medicines that may have an unwanted effect on the electrical activity of the heart (torsades de pointes), such as bepridil, chloroquine, clarithyromycin, halofantrine, haloperidol, methadone, moxifloxacin or pimozide.
- medicines used to reduce the blood's ability to clot, such as warfarin or dabigatran.
- medicines used to treat high blood pressure and other heart conditions, such as digoxin.
- St. John's wort (also known as *Hypericum perforatum*), a herbal medicine used to treat depression and other conditions.

You should also tell your doctor if you are already taking Scemblix and you are prescribed any new medicine that you have not taken previously during Scemblix treatment.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

**Scemblix with food and drink**
Do not take Scemblix with food. Take it at least 2 hours after and 1 hour before any food. For more information, see "When to take Scemblix" in section 3.

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Scemblix may harm your unborn baby. If you are a woman who could become pregnant, your doctor will discuss with you the potential risks of taking Scemblix during pregnancy or breast-feeding.

If you are a woman who could become pregnant, your doctor may perform a pregnancy test before starting treatment with Scemblix.

If you do become pregnant, or think you may be pregnant, after starting treatment with Scemblix, tell your doctor straight away.

Breast-feeding
It is not known if Scemblix passes into breast milk. It is recommended that you do not breast-feed while you are taking Scemblix and for at least 3 days after you stop taking it.

Contraceptive advice for women
If you are a woman who could become pregnant, you should use an effective method of contraception during treatment with Scemblix and for at least 3 days after you stop taking it to avoid becoming pregnant. Ask your doctor about effective methods of contraception.

**Driving and using machines**
Scemblix has no or negligible influence on the ability to drive and use machines. If you experience side effects (such as dizziness or visual disorders) with a potential impact on the ability to safely drive or use any tools or machines after taking this medicine, you should refrain from these activities until the effect has disappeared.

**Scemblix contains**
- **Lactose:** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- **Sodium:** Scemblix contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially "sodium free".

## 3. How to take Scemblix

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose prescribed by your doctor.

**How much Scemblix to take**
Your doctor will tell you exactly how many Scemblix tablets you should take per day, and how to take them.

The recommended total daily dose of Scemblix is 80 mg (2 tablets of Scemblix 40 mg per day). You may take your daily dose:
- Once daily: Take 2 tablets together at approximately the same time each day,

OR
- Twice daily: Take 1 tablet, then take another one approximately 12 hours later.

You should not change the Scemblix dose or schedule without first talking to your doctor.

Depending on how you respond to treatment, your doctor may ask you to change to a lower dose or to temporarily or permanently stop the treatment.

**When to take Scemblix**
Take Scemblix:
- at least 2 hours after any food
- then wait at least 1 hour before eating again.

Taking Scemblix at the same time each day will help you to remember when to take your medicine.

**How to take Scemblix**
Swallow Scemblix tablets whole with a glass of water. Do not break, crush or chew the tablets.

**How long to take Scemblix**
Continue taking Scemblix for as long as your doctor tells you. This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.
If you have questions about how long to take Scemblix, talk to your doctor or pharmacist.

**If you take more Scemblix than you should**
If you have taken more Scemblix than you should have, or if someone else accidentally takes your medicine, contact a doctor for advice straight away. Show them the pack of Scemblix. Medical treatment may be necessary.

**If you forget to take Scemblix**
Do not take a double dose to make up for the forgotten tablets.

<u>If you take Scemblix once daily</u>
If the dose is missed by less than 12 hours, take your recommended dose. If you forget to take Scemblix by more than 12 hours, skip the missed dose and take the next one as usual.

<u>If you take Scemblix twice daily</u>
If the dose is missed by less than 6 hours, take your recommended dose. If you forget to take Scemblix by more than 6 hours, skip the missed dose and take the next one as usual.

**If you stop taking Scemblix**
Do not stop taking Scemblix unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Some side effects could be serious**
If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

**Very common** (may affect more than 1 in 10 people)
- spontaneous bleeding or bruising (signs of low level of platelets, thrombocytopenia)
- fever, sore throat, frequent infections (signs of low level of white blood cells, neutropenia)

**Common** (may affect up to 1 in every 10 people)
- irregular heart-beat, change in the electrical activity of the heart (prolongation of the QT interval)

**Uncommon** (may affect up to 1 in every 100 people)
- fever above 38°C associated with a low level of white blood cells (febrile neutropenia)
- low levels of all types of blood cells (pancytopenia)

**Other possible side effects**
Other side effects include the following listed below. If these side effects become severe, please tell your doctor or pharmacist.

**Very common** (may affect more than 1 in 10 people)
- nose and throat infections (upper respiratory tract infection)
- tiredness, fatigue, pale skin (potential signs of low level of red blood cells, anaemia)
- headache, dizziness, chest pain or shortness of breath (signs of high blood pressure, hypertension)
- headache
- dizziness
- shortness of breath, laboured breathing (signs of dyspnoea)
- cough
- vomiting
- diarrhoea
- nausea
- abdominal pain
- rash
- itching (pruritus)
- pain in muscles, bones or joints (musculoskeletal pain)
- joint pain (arthralgia)
- tiredness (fatigue)
- generalised swelling (oedema)
- fever (pyrexia)

**Common** (may affect up to 1 in every 10 people)
- fever, coughing, difficulty breathing, wheezing (signs of lower respiratory tract infections)
- influenza
- loss of appetite
- blurred vision
- dry eyes
- palpitations
- chest pain, cough, hiccups, rapid breathing, fluid collection between the lungs and chest cavity which, if severe, could make you breathless (pleural effusion)
- chest pain (non-cardiac chest pain)
- severe upper stomach pain (sign of inflamed pancreas, pancreatitis)
- itchy rash (urticaria)

**Uncommon** (may affect up to 1 in every 100 people)
- allergic reaction which may include rash, hives, difficulty breathing or low blood pressure (hypersensitivity)

**Abnormal blood test results**
During Scemblix treatment, the results of blood tests may be abnormal, which can give your doctor information on the function of your organs. For example:

**Very common** (may affect more than 1 in 10 people)
- high level of the enzymes lipase and amylase (pancreas function)
- high level of the enzymes transaminases, which include alanine aminotransferase (ALT), aspartate aminotransferase (AST) and gamma-glutamyltransferase (GGT) (liver function)
- high level of fats/lipids (dyslipidaemia)

**Common** (may affect up to 1 in every 10 people)
- high level of bilirubin (liver function)
- high level of creatine phosphokinase (muscles function)

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Scemblix

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Do not use this medicine if you notice any damage to the packaging or if there are any signs of tampering.

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 protect the environment.

## 6. Contents of the pack and other information

**What Scemblix contains**
- The active substance is asciminib.
  Each 20 mg film-coated tablet contains 20 mg asciminib (as asciminib hydrochloride). Each 40 mg film-coated tablet contains 40 mg asciminib (as asciminib hydrochloride).
- The other ingredients are:
  - In the tablet core: lactose monohydrate, microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, magnesium stearate and colloidal silicon dioxide
  - In the film coating: polyvinyl alcohol, titanium dioxide (E171), talc, lecithin (E322), xanthan gum (E415) and iron oxides (E172, see below).
    - Scemblix 20 mg film-coated tablets contain iron oxide red and iron oxide yellow.
    - Scemblix 40 mg film-coated tablets contain iron oxide red and iron oxide black.

  See “Scemblix contains lactose and sodium” in section 2.

**What Scemblix looks like and contents of the pack**
Scemblix 20 mg film-coated tablets: pale yellow, round, biconvex tablet with bevelled edges of approximately 6 mm diameter, debossed with company logo on one side and “20” on the other side.

Scemblix 40 mg film-coated tablets: violet white, round, biconvex tablet with bevelled edges of approximately 8 mm diameter, debossed with company logo on one side and “40” on the other side.

Scemblix is available in packs containing 20 or 60 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ, United Kingdom.

**Manufacturer**
Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland

Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ, United Kingdom.

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