

Starting and keeping up your treatment with Scemblix®▼(asciminib)

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A guide for managing your CML treatment

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>.

By reporting side effects, you can help provide more information on the safety of this medicine.

This patient support booklet has been funded and developed by Novartis Pharmaceuticals UK Ltd.

This leaflet is intended for patients who have been prescribed Scemblix only.

 NOVARTIS

 **SCEMBLIX®▼**
(asciminib) 20 mg, 40 mg tablets

About this guide

This guide is designed to help you get the most out of your treatment with Scemblix (asciminib) for Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase by giving you:



Information you need to help you manage your treatment



Tips for talking to your doctor and other members of your healthcare team

This booklet does not replace the patient information leaflet or advice you have received from your healthcare professional.



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Throughout this guide, Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase is referred to as CML

Who is it for?

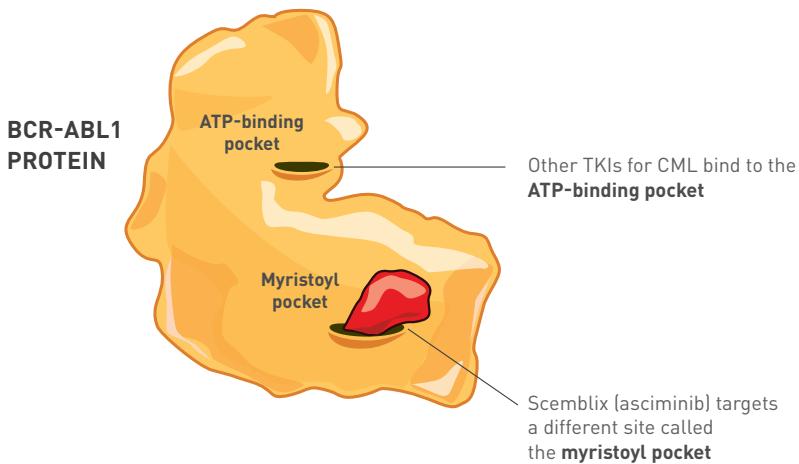
Scemblix is used to treat adults with CML, who were previously treated with two or more medicines called tyrosine kinase inhibitors (TKIs).

Your doctor may have prescribed Scemblix, also known as asciminib, because:

- ▶ Side effects from a previous TKI were challenging to manage (your doctor may refer to this as drug intolerance)
- ▶ Your previous TKI stopped working for you (your doctor may refer to this as drug resistance)
- ▶ You experienced a combination of drug intolerance and drug resistance

How does it work?

In CML, TKIs bind to the BCR-ABL1 protein, causing a change that slows down or stops the activity of this protein. Traditional TKIs bind to a location called the ATP-binding pocket in the BCR-ABL1 protein (see diagram below). Scemblix is the first and only treatment for CML that targets a different site, the myristoyl pocket.



How do I take it?

Your doctor will tell you exactly how many tablets you should take per day and how to take them.



Not actual size



The recommended total dose is 80 mg per day (2 tablets of 40 mg each).

Your doctor may tell you to 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



Swallow the tablets whole with a glass of water.

DO NOT break, crush or chew the tablets.



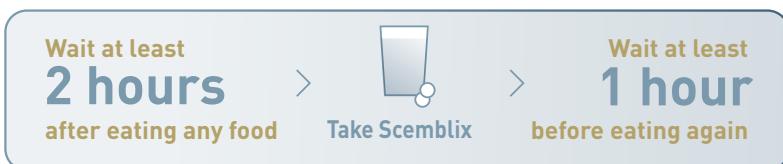
DO NOT take with food.

Food may change the way your body absorbs Scemblix.

If taken together, food can decrease the amount of medication in your blood.

Take it:

- At least **2 hours** after eating any food
- Then wait at least **1 hour** before eating any food again



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

What if I miss a dose?

If you take it **once daily** and miss a dose by more than 12 hours:

- Skip the missed dose
- Take your next dose at your regular scheduled time

If you take it **once daily** and miss a dose by less than 12 hours:

- Take your recommended dose as soon as you remember

If you take it **twice daily** and miss a dose by more than 6 hours:

- Skip the missed dose
- Take your next dose at your regular scheduled time

If you take it **twice daily** and miss a dose by less than 6 hours:

- Take your recommended dose as soon as you remember

If you vomit after taking a dose, call your doctor straight away.

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.

Should I follow any storage instructions?



Scemblix should not be stored at a temperature higher than 25°C. Store in the original package in order to protect from moisture.



It's important to take your medicine exactly as your doctor prescribed.

It is natural to have concerns about side effects when starting a new treatment. Like most medicines, Scemblix can cause side effects.

Keep in mind that everyone experiences treatment differently.

Knowing what you can expect is important. Talk with your doctor about what you can do to help manage any possible side effects. Together, you can make a plan.

What are the most common side effects?*

Serious side effects

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)

Uncommon (may affect up to 1 in every 100 people)

- Irregular heart-beat, change in the electrical activity of the heart (prolongation of the QT interval)
- Fever above 38°C associated with a low level of white blood cells (febrile neutropenia)



Tell your doctor right away if you experience any side effects.

Your doctor may change your dose, temporarily stop or permanently stop treatment if you have certain side effects.

*Side effects shown here are not listed in any particular order.

Other side effects

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
- Cough
- Vomiting
- Diarrhoea
- Nausea
- Abdominal pain
- Rash
- Pain in muscles, bones or joints (musculoskeletal pain)
- Joint pain (arthralgia)
- Tiredness (fatigue)
- Itching (pruritus)

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)
- Shortness of breath, laboured breathing (signs of dyspnoea)
- Chest pain (non-cardiac chest pain)
- Severe upper stomach pain (sign of inflamed pancreas, pancreatitis)
- Itchy rash (urticaria)
- Fever (pyrexia)
- Generalised swelling (oedema)

For more information, consult the Scemblix Patient Information Leaflet (PIL) at: <https://www.medicines.org.uk/emc/product/13818/pil#gref>

Certain medications may interact with Scemblix. Before starting Scemblix, tell your doctor if you are taking any other medicines. This includes medicines prescribed by other doctors you see, as well as medicines, herbs and supplements that you buy without a prescription.

What you need to know before you take Scemblix

Do not take it:

- If you are **allergic to asciminib or any of the other ingredients** of this medicine

Tell your CML doctor or pharmacist immediately if you are told that you have any of the following during treatment:

- **Myelosuppression** (decreased bone marrow activity, resulting in a reduced number of white blood cells, red blood cells and platelets). Signs include weakness, spontaneous bleeding or bruising and frequent infections with signs such as fever, chills, sore throat or mouth ulcers
- **Pancreatic toxicity** (damage to the pancreas) with high levels of enzymes called lipase and amylase that show in blood tests
- **Prolongation of the QT interval** (an irregular heartbeat or an abnormal electrical signal) with a heart disorder or a heart rhythm disorder
- **Hypokalaemia or hypomagnesaemia** (low levels of potassium or magnesium) that show in blood tests
- **Torsades de pointes** (an unwanted effect on the function of the heart) if you are being treated with other medicines
- **Hypertension** (high blood pressure). Signs include headache, dizziness, chest pain or shortness of breath

Warnings and precautions

Talk to your doctor or pharmacist before taking it if any of the following apply to you:

- If you have or have ever had **severe upper stomach pain** (inflamed pancreas, pancreatitis)
- 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

These are not all of the possible side effects of Scemblix. For more information, consult the Scemblix Patient Information Leaflet (PIL) at: <https://www.medicines.org.uk/emc/product/13818/pil#gref>

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. Please refer to the patient information leaflet for more details.

Is it safe during pregnancy?

If you:

- are pregnant or breast-feeding
- think you may be pregnant
- are planning to have a baby

Ask your doctor or pharmacist for advice before taking this medicine.

If you 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.**



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

Monitoring your response

To see how you are responding to treatment, your doctor will regularly monitor your condition. It is important to follow the monitoring schedule as prescribed.

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 pancreatic enzymes (amylase and lipase)
- The levels of electrolytes (potassium and magnesium)
- Your heart rate and blood pressure



Ask your doctor what monitoring tests you will need in the first few months of treatment. **This may help you plan your schedule**

Tracking results

Tracking test results can help you and your doctor see how you are responding to treatment over time.

A PCR test will help you and your doctor track your BCR-ABL1 level over time. You and your doctor will want to see this level decrease.



Working with your healthcare team

Working with your doctor and other members of your healthcare team helps you achieve a common goal: your best care.

Here are some tips to help you work with your healthcare team:

- Remember that your doctor wants to hear from you. Let your doctor know how you are feeling, any challenges you may be having, as well as your successes while on treatment
- Prepare for your doctor's appointments to make sure you get the most out of each visit. For example, write down your questions before the visit
- Talk with your doctor about your test results. Once your doctor has the results of your monitoring tests, ask what the results mean. This understanding will help you track your progress over time

Questions to ask your doctor



Here are a few questions you may want to ask your doctor as you start treatment. These can help you know what to expect, so you can plan ahead. Use the space below to write down the answers

Why did you prescribe me Scemblix?

What goals are we setting/aiming for with this treatment?

What do I need to know about taking Scemblix?

What are the possible side effects?

What monitoring tests do I need?

How often is monitoring necessary?

How can I find additional resources and support?

Write any other questions below to help you remember

Useful resources

Learn more about CML and find support groups:

CML Support



Originally established in 1999 by two patients diagnosed with Ph+ CML, CML Support patient advocacy group provides support, advice and up-to-date information about the disease and its treatment options to the patients diagnosed with CML. CML Support is the UK's only charity with an exclusive focus on people diagnosed with Ph+ Chronic Myeloid Leukaemia and run by patients on a voluntary basis. The group works alongside healthcare professionals to help patients get the best and most appropriate care possible and maintains links with other patient groups worldwide.

<https://cmlsupport.org.uk/>

Blood Cancer UK



Can help you understand different types of blood cancer, including CML. Available information will let you know what you can expect at diagnosis, what treatment options are available and provides support to managing life with blood cancer.

<https://bloodcancer.org.uk>

The links on this page lead to third-party webpages, which Novartis have no control of.

CML UK Facebook group

chronic myeloid leukaemia



Chronic Myeloid Leukaemia or CML UK is a group set up to enable UK-based CML patients and carers, or those just with an interest, to connect and share their experiences on an informal basis.

<https://www.facebook.com/groups/cmluk>

Leukaemia Care

Leukaemia Care
YOUR Blood Cancer Charity

Leukaemia Care is a national blood cancer support charity. For over 50 years the Leukaemia Care team have been dedicated to ensuring that everyone diagnosed with leukaemia and related blood cancer types receives the best possible diagnosis and treatment. The organisation provides information, advice and support for patients, but also carers and families. The Leukaemia Care team have created a variety of CML-specific tools to help patients engage with the community and learn more about their diagnosis, including information booklets, support groups, webinars, as well as helpline, counselling and buddy programmes and other helpful platforms to support patients on their CML journey.

<https://www.leukaemiacare.org.uk/>



For more information, consult the
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at www.medicines.org.uk/emc

