Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrSCEMBLIX®

Asciminib tablets

This Patient Medication Information is written for the person who will be taking **SCEMBLIX®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SCEMBLIX**, talk to a healthcare professional.

What SCEMBLIX is used for:

SCEMBLIX is used in adults to treat Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. The Ph+ CML is newly detected or previously treated with other similar medicines called tyrosine kinase inhibitors.

How SCEMBLIX works:

SCEMBLIX blocks the action of a protein (called BCR::ABL1) of the abnormal white blood cells and stops their division and growth.

The ingredients in SCEMBLIX are:

Medicinal ingredient: asciminib (as asciminib hydrochloride)

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropylcellulose, iron oxide (yellow and red for 20 mg film-coated tablets; black and red for 40 mg film-coated tablets), lactose monohydrate, lecithin, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, talc, titanium dioxide, xanthan gum.

SCEMBLIX comes in the following dosage form:

Tablets: 20 mg and 40 mg

Do not use SCEMBLIX if:

- you are allergic to asciminib or any other ingredients in SCEMBLIX

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SCEMBLIX. Talk about any health conditions or problems you may have, including if you:

- 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. You will be carefully checked by your healthcare professional for signs of this infection before starting treatment.
- have a heart problem, such as heart failure (heart does not pump blood as well as it should)
- have a heart rhythm problem, such as an irregular heartbeat or an abnormal electrical signal called prolongation of the QT interval.
- are taking medicines that may have an unwanted effect on the function of the heart (torsades de pointes). See **The following may interact with SCEMBLIX** section below for information on these medicines.

Other warnings you should know about:

Female patients

Pregnancy and birth control
- If you are pregnant, think you might be pregnant or are planning to have a baby ask your healthcare professional for advice before taking this medicine. They will discuss with you the potential risks of taking SCEMBLIX during pregnancy or breast-feeding.
- Avoid becoming pregnant while taking SCEMBLIX. It can harm your unborn baby.
- Use effective birth control during treatment with SCEMBLIX and for at least 1 week after the last dose. Ask your healthcare professional about effective birth control options.
- **For women who can get pregnant**: A pregnancy test should be done before you start treatment with SCEMBLIX.
- Tell your healthcare professional right away if you become pregnant or think you are pregnant after starting treatment with SCEMBLIX.

Breast-feeding
- Do NOT breast-feed during treatment with SCEMBLIX and for at least 1 week after the last dose. It is not known if SCEMBLIX passes into your breast milk.
- Talk to your healthcare professional about the best way to feed your baby during treatment with SCEMBLIX.

Male patients

Birth control
- Use effective method of birth control (including a barrier method) during treatment with SCEMBLIX. Continue using effective method of birth control for at least 1 week after the last dose.
- Tell your healthcare professional right away if your partner becomes pregnant.

Fertility

Treatment with SCEMBLIX may affect your ability to have children. Talk to your healthcare professional if you have concerns about this.

Check-ups and testing

Your healthcare professional will regularly monitor your condition to check that the treatment is working for you.

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), every 2 weeks for the first 3 months of treatment, then monthly as needed.
- The levels of pancreas enzymes (amylase and lipase), every month or as needed to check for problems with your pancreas.
- The levels of electrolytes (potassium, magnesium).
- Your heart rate and your blood pressure.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SCEMBLIX:

- Medicines used to treat seizures such as carbamazepine, phenobarbital or phenytoin.
- Medicines used to treat tuberculosis, such as rifampicin.
- Itraconazole as oral solution, a medicine used to treat fungal infections.
- Medicines used to treat pain or used 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 activities of the heart (torsades de pointes), such as bepridil, chloroquine, clarithromycin, 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 or heart problems, such as digoxin.
- St. John's wort (also known as Hypericum perforatum), an herbal medicine used to treat depression and other conditions.
- Medicines used to treat severe inflammation of the bowel or severe rheumatic or painful joint inflammation, such as sulfasalazine and colchicine.
- Medicines used to treat cancer, severe rheumatic joint inflammation, or psoriasis, such as methotrexate.
- A medicine used to reduce blood cholesterol levels called rosuvastatin.

If you are already taking SCEMBLIX and you are prescribed any new medicine, tell your healthcare professional you are taking SCEMBLIX.

How to take SCEMBLIX:

- Take SCEMBLIX exactly as your healthcare professional tells you. They will tell you exactly how many SCEMBLIX tablets to take and how to take them. Check with your healthcare professional if you are not sure.
- Swallow SCEMBLIX tablets whole. Do NOT break, crush or chew SCEMBLIX tablets.
- Do NOT take SCEMBLIX with food. Take SCEMBLIX:
  - At least 2 hours after any food
  - Then wait at least 1 hour before eating again
- Try to take SCEMBLIX at the same time each day. This will help you remember when to take it.
- Continue taking SCEMBLIX for as long as your healthcare professional tells you. If you have questions about how long to take SCEMBLIX, talk to your healthcare professional.

- This is a long-term treatment, possibly lasting for months or years. Your healthcare professional will regularly monitor your condition to check that the treatment is working for you.

Usual dose:

The usual total daily dose of SCEMBLIX is 80 mg. You may take your daily dose either:

- Once daily: 80 mg at approximately the same time each day.
  OR
- Twice daily: 40 mg, every 12 hours.

Do NOT take more than the recommended dose prescribed by your healthcare professional.

Depending on how you respond to treatment with SCEMBLIX, your healthcare professional may reduce your dose, temporarily stop or permanently stop the treatment. You should not change the SCEMBLIX dose or schedule without first talking to your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much SCEMBLIX, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you take SCEMBLIX once daily

If you forget to take SCEMBLIX by more than 12 hours, skip the missed dose. Take the next dose at the usual time.

If you take SCEMBLIX twice daily

If you forget to take SCEMBLIX by more than 6 hours, skip the missed dose. Take the next dose at the usual time.

Possible side effects from using SCEMBLIX:

These are not all the possible side effects you may have when taking SCEMBLIX. If you experience any side effects not listed here, tell your healthcare professional.

- Nose and throat infections (upper respiratory tract infection)
- Headache
- Dizziness
- Cough
- Vomiting
- Diarrhea
- Nausea
- Abdominal pain

- Constipation
- Itching
- Pain in muscles, bones, joints or chest (musculoskeletal pain)
- Joint pain
- Tiredness (fatigue)
- Fever, coughing, difficulty breathing, wheezing (signs of lower respiratory tract infections)
- Influenza
- Loss of appetite
- Blurred vision
- Dry eyes
- Palpitations
- Shortness of breath, laboured breathing
- Generalized swelling
- Fever

Abnormal blood test results:

During SCEMBLIX treatment, the results of blood tests may be abnormal. This can give your healthcare professional information on the function of your organs. For example:

- High level of fats/lipids (dyslipidemia)
- High level of the enzymes lipase and amylase (pancreas function)
- High level of the enzymes transaminases (liver function)
- High level of bilirubin (liver function)
- High level of creatine phosphokinase (muscles function)

Your healthcare professional will decide when to perform blood tests and will interpret the results. Tell your healthcare professional if the side effects become bad enough.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very Common			
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations			√
Myelosuppression (a large decrease in the production of blood cells and platelets by the bone marrow): bleeding, bruising, chills, fatigue, fever,		√	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
infections, weakness, shortness of breath or other signs of frequent infections			
Rash from allergic origin, including urticaria: Itchy skin with or without rash, hives		√	
Common			
Hypothyroidism (underactive/low thyroid): Weight gain, tiredness, hair loss, muscle weakness, feeling cold, dry skin, constipation, puffy face, heavier than normal or irregular menstrual periods, enlarged thyroid gland		√	
Pleural effusion (fluid around the lungs): chest pain, difficult or painful breathing, cough			√
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen			√
Uncommon			
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise		√	
Febrile neutropenia: fever above 38°C associated with a low level of white blood cells			√
Hypersensitivity (allergic reaction): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, watery eyes		√	
Prolongation of the QT interval: irregular heartbeat,			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
change in the electrical activity of the heart			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Do not store above 25°C
- Keep in the original package. Protect from moisture.
- Do not take this medicine after the expiry date, which is stated on the box.
- Keep out of reach and sight of children. Do not take this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Ask your pharmacist how to dispose of medicines you no longer use.

If you want more information about SCEMBLIX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.novartis.ca), or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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