Product Information Guide for SCEMBLIX

How Supplied/Storage and Handling

SCEMBLIX is supplied as 20-mg, 40-mg, and 100-mg film-coated tablets.

Tablet Strength	Tablets per Bottle	NDC
20 mg film-coated tablets	60 film-coated tablets	0078-1091-20
40 mg film-coated tablets	60 film-coated tablets	0078-1098-20
100 mg film-coated tablets*	60 film-coated tablets	0078-1196-20

*For adult patients with Philadelphia chromosome-positive chronic myeloid leukemia [Ph+ CML] in chronic phase [CP] with the T315I mutation/those requiring 200 mg bid dose.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Dispense and store in the original container in order to protect from moisture.

Distributors

SCEMBLIX is available for purchase through one of the specialty distributors below:

Cencora	Cardinal Health	McKesson Plasma and Biologics	McKesson Specialty
800-746-6273	855-855-0708	877-625-2566	855-477-9800

Key Product Distribution Information: Due to the very limited expected use, the 100-mg tablet will be available via dropship for each prescription. Please contact your specialty distributor to provide access for your patients.

For providers without an in-house pharmacy† or who choose to send their prescriptions to a mail order pharmacy, prescriptions for patients with the T315I mutation can be filled by one of the two in-network national specialty pharmacies for SCEMBLIX, Biologics (800-850-4306) or Onco360 (877-662-6633).

†Novartis does not recommend or require the use of any particular pharmacy.

Please see full Prescribing Information.

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Specialty Pharmacy Network

The network includes 2 full-service specialty pharmacy partners, in-office dispensing pharmacies, and health system specialty pharmacies[‡§]:

Biologics By McKesson

www.biologics.mckesson.com
Phone 1-800-850-4306
Fax 1-800-823-4506

Onco360® ONCOLOGY PHARMACY

www.onco360.com
Phone 1-877-662-6633
Fax 1-877-662-6355

If you have any questions, please contact your Novartis Account Representative or our Customer Service Center at 1-888-NOW-NOVA.

Visit www.scemblix-hcp.com for more information.

[‡]Novartis does not recommend or require the use of any particular pharmacy.
[§]Account-owned pharmacy.

Please see full Prescribing Information.

INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

SCEMBLIX® is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
  - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)
- Previously treated Ph+ CML in CP
- Ph+ CML in CP with the T315I mutation

IMPORTANT SAFETY INFORMATION

Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Perform complete blood counts every 2 weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression
- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCEMBLIX
- Assess serum lipase and amylase levels monthly during treatment with SCEMBLIX, or as clinically indicated. Monitor patients for signs and symptoms of pancreatic toxicity. Perform more frequent monitoring in patients with a history of pancreatitis
- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Hypertension

- Hypertension, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Monitor and manage hypertension using standard antihypertensive therapy during treatment with SCEMBLIX as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypertension

Hypersensitivity

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX. Reactions included rash, edema, and bronchospasm
- Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypersensitivity

Cardiovascular Toxicity

- Cardiovascular toxicity (including ischemic cardiac and central nervous system conditions; and arterial thrombotic and embolic conditions) and cardiac failure have occurred in patients receiving SCEMBLIX. Some toxicities were grade 3/4 and 5 fatalities were reported

INDICATIONS and IMPORTANT SAFETY INFORMATION (cont)

Cardiovascular Toxicity (cont)

- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3/4
- Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated
- For grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of cardiovascular toxicity

Embryo-Fetal Toxicity

- SCEMBLIX can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus if SCEMBLIX is used during pregnancy or if the patient becomes pregnant while taking SCEMBLIX
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with SCEMBLIX. Advise females to use effective contraception during treatment and for at least 1 week after the last SCEMBLIX dose

ADVERSE REACTIONS

- Most common adverse reactions (≥20%) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain, arthralgia, and diarrhea
- Most common select laboratory abnormalities (≥20%) were lymphocyte count decreased, leukocyte count decreased, platelet count decreased, neutrophil count decreased, calcium corrected decreased, lipase increased, cholesterol increased, uric acid increased, alanine aminotransferase increased, alkaline phosphatase increased, hemoglobin decreased, triglycerides increased, creatine kinase increased, amylase increased, and aspartate aminotransferase increased

DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, and BCRP. Asciminib is a CYP3A4 substrate
- Closely monitor for adverse reactions during concomitant use of strong CYP3A4 inhibitors and SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of itraconazole oral solution containing hydroxypropyl-β-cyclodextrin and SCEMBLIX at all recommended doses
- Closely monitor for adverse reactions during concomitant use of certain CYP3A4 substrates and SCEMBLIX at 80 mg total daily dose. Avoid use of SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of CYP2C9 substrates and SCEMBLIX at all recommended doses. If coadministration with 80 mg total daily dose is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information. If coadministration with 200 mg twice daily is unavoidable, consider alternative therapy with a non-CYP2C9 substrate
- Closely monitor for adverse reactions during concomitant use of certain P-gp substrates and SCEMBLIX at all recommended doses
- Avoid concomitant use of rosuvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other BCRP substrates and SCEMBLIX at all recommended doses

NOVARTIS

SCEMBLIX®
(asciminib) 20 mg, 40 mg tablets

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080