

# 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 Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) patients 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

## Specialty Pharmacy Network and Other Pharmacy Outlets

A dedicated Specialty Pharmacy Network includes 2 full-service specialty pharmacy providers. SCEMBLIX is also available through in-office dispensing pharmacies and health system pharmacies†:



[www.biologics.mckesson.com](http://www.biologics.mckesson.com)  
Phone 1-800-850-4306  
Fax 1-800-823-4506



[www.onco360.com](http://www.onco360.com)  
Phone 1-877-662-6633  
Fax 1-877-662-6355

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

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](http://www.scemblix-hcp.com) for more information.

Please see Important Safety Information and click [here](#) for full Prescribing Information.

## INDICATION and IMPORTANT SAFETY INFORMATION

### INDICATIONS

SCSEMBLIX® (asciminib) tablets is indicated for the treatment of adult patients with:

- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)
- 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 SCSEMBLIX
- 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 SCSEMBLIX as described in the prescribing information

#### Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and asymptomatic elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCSEMBLIX
- Assess serum lipase and amylase levels monthly during treatment with SCSEMBLIX, 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 SCSEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCSEMBLIX as described in the prescribing information

#### Hypertension

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

#### Hypersensitivity

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCSEMBLIX. 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 SCSEMBLIX 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 SCSEMBLIX. Some toxicities were grade 3/4 and 3 fatalities were reported

### Cardiovascular Toxicity (continued)

- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3
- 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 ( $\geq 20\%$ ) were upper respiratory tract infections, musculoskeletal pain, headache, fatigue, nausea, rash, and diarrhea
- Most common laboratory abnormalities ( $\geq 20\%$ ) were platelet count decreased, triglycerides increased, neutrophil count decreased, hemoglobin decreased, creatine kinase increased, alanine aminotransferase increased, lipase increased, amylase increased, aspartate aminotransferase increased, uric acid increased, and lymphocyte count decreased

### DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, OATP1B, 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- $\beta$ -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 or atorvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other OATP1B or BCRP substrates and SCEMBLIX at all recommended doses

Please click [here](#) for full Prescribing Information.

