

SAFETY, DOSING, AND ADMINISTRATION



SCEMBLIX[®]
(asciminib) 20 mg, 40 mg tablets

INDICATION

SCEMBLIX 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)

IMPORTANT SAFETY INFORMATION for SCEMBLIX

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

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

How to use this guide

- 1 This document summarizes the starting doses and safety profile of SCSEMBLIX and offers guidance on dose modification for management of adverse reactions
- 2 The presented adverse reaction-management strategies are designed to be a reference and are not intended to supersede your clinical judgment in managing individual patients
- 3 Not all adverse reactions associated with SCSEMBLIX are discussed in this guide
- 4 An informational section entitled Patient Counseling has been included to help you reinforce important points to counsel patients about potential adverse reactions

IMPORTANT SAFETY INFORMATION for SCSEMBLIX (cont)

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

SCSEMBLIX overview

In ASCSEMBL, a study for patients with Ph+ CML-CP, previously treated with ≥ 2 TKIs:

- At Week 24, SCSEMBLIX demonstrated 25% MMR rate (n=157) vs 13% (n=76) with bosutinib (difference^a: 12% [95% CI, 2.2-22; P=0.029^b])^{1,*}
- SCSEMBLIX more than doubled the MMR rate at Week 96 vs bosutinib (38% vs 16%; difference^a: 22% [95% CI, 11-33; P=0.001])¹
- More patients achieved CCyR at Week 24 with SCSEMBLIX vs bosutinib (41% vs 24%; difference: 17% [95% CI, 3.6-31])^{1,c}
- More patients achieved MR4 and MR4.5 at Week 96 with SCSEMBLIX vs bosutinib (17% vs 11% and 11% vs 5%, respectively)²

ASCSEMBL study design¹

- Multicenter, 2:1 randomized (stratified by MCyR status), active-controlled, and open-label study in adults (N=233) with Ph+ CML-CP, previously treated with 2 or more TKIs
- 157 patients received SCSEMBLIX at 40 mg bid and 76 patients received bosutinib at 500 mg qd until unacceptable toxicity or treatment failure occurred^d
- The median duration of treatment was 24 months (range: 0 to 46 months) for patients receiving SCSEMBLIX and 7 months (range: 0 to 43 months) for patients receiving bosutinib

bid, twice daily; CCyR, complete cytogenetic response; CML, chronic myeloid leukemia; MCyR, major cytogenetic response; MMR, major molecular response; Ph+, Philadelphia chromosome-positive; qd, once daily; TKIs, tyrosine kinase inhibitors.

MMR was defined as $BCR::ABL1^{IS} \leq 0.1\%$.¹

CCyR was defined as 0% of Philadelphia chromosome-positive metaphases in bone marrow aspirate with at least 20 examined.¹

MCyR is defined as 0% to 35% Ph+ metaphases.³

MR4 is defined as $BCR::ABL1^{IS} \leq 0.01\%$.⁴

MR4.5 is defined as $BCR::ABL1^{IS} \leq 0.0032\%$.⁴

*Primary end point.

^aEstimated using a common risk difference stratified by baseline MCyR status.

^bEstimated using a Cochran-Mantel-Haenszel 2-sided test stratified by baseline MCyR status.

^cCCyR analysis based on patients who were not in CCyR at baseline.

^dPatients will continue to receive study treatment for up to 96 weeks after the last patient's first dose or 48 weeks after the last patient switches to SCSEMBLIX, whichever is longer.

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

SCEMBLIX has a well-established tolerability profile over time¹

All-grade adverse reactions (occurring in ≥10% of patients in any treatment arm) at the Week 96 analysis¹

Adverse reaction	SCEMBLIX (n=156)		Bosutinib (n=76)	
	All grades %	Grade 3 or 4 %	All grades %	Grade 3 or 4 %
URTI ^a	26	0.6	12	1.3
Musculoskeletal pain ^b	24	2.6	17	1.3
Headache ^c	21	1.9	16	0
Fatigue ^d	20	0.6	11	1.3
Rash ^e	18	0.6	30	8
Hypertension ^f	14	7	5	3.9
Abdominal pain ^g	14	0	24	2.6
Diarrhea ^h	13	0	72	11
Arthralgia	13	0.6	3.9	0
Nausea	12	0.6	46	0

Serious adverse reactions occurred in 18% of patients who received SCEMBLIX. Serious adverse reactions in ≥1% included cardiac failure congestive (1.9%), pyrexia (1.9%), urinary tract infection (1.9%), headache (1.3%), and thrombocytopenia (1.3%). Two patients (1.3%) had a fatal adverse reaction, one each for mesenteric artery thrombosis and ischemic stroke.¹

URTI, upper respiratory tract infection.

^aUpper respiratory tract infection includes: nasopharyngitis, upper respiratory tract infection, rhinitis, pharyngitis, respiratory tract infection, and pharyngotonsillitis.

^bMusculoskeletal pain includes: pain in extremity, back pain, myalgia, non-cardiac chest pain, neck pain, bone pain, spinal pain, arthritis, musculoskeletal pain, and musculoskeletal chest pain.

^cHeadache includes: headache and post-traumatic headache.

^dFatigue includes: fatigue and asthenia.

^eRash includes: rash, rash maculopapular, dermatitis acneiform, rash pustular, eczema, dermatitis, skin exfoliation, dermatitis exfoliative generalized, rash morbilliform, drug eruption, erythema multiforme, and rash erythematous.

^fHypertension includes: hypertension and hypertensive crisis.

^gAbdominal pain includes: abdominal pain, abdominal pain upper, abdominal discomfort, abdominal pain lower, abdominal tenderness, and epigastric discomfort.

^hDiarrhea includes: diarrhea and colitis.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (cont)

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

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

Laboratory abnormalities

Select laboratory abnormalities (≥10%) that worsened from baseline at the Week 96 analysis¹

Laboratory abnormality	SCEMBLIX ^a		Bosutinib ^a	
	All grades %	Grade 3 or 4 %	All grades %	Grade 3 or 4 %
Platelet count decreased	46	24	36	12
Triglycerides increased	44	5	30	2.6
Neutrophil count decreased	43	22	33	15
Hemoglobin decreased	37	2	54	5
Creatine kinase increased	30	2.6	24	5
ALT increased	26	0.6	50	16
Uric acid increased	21	6	18	2.6
AST increased	21	1.9	46	7
Lymphocyte count decreased	20	3.3	34	2.6
Phosphate decreased	18	6	20	7
Corrected Calcium decreased	16	0.6	22	0
Lipase increased	15	4.5	18	7
Creatinine increased	15	0	26	0
Amylase increased	13	1.3	13	0
ALP increased	13	0	12	0
Bilirubin increased	12	0	3.9	0
Cholesterol increased	12	0	8	0
Potassium decreased	11	0	9	0

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase.

^aThe denominator used to calculate the rate for SCEMBLIX and bosutinib varied from 152 to 156 and 75 to 76, respectively, based on the number of patients with a baseline value and at least one post-treatment value.

The SCEMBLIX safety and tolerability profile at Week 96 was consistent and comparable overall to that of the Week 24 analyses, with no new or worsening safety findings.²

A once-daily dosing option to accommodate your patients¹

Patients previously treated with ≥2 TKIs:

80 mg once daily

There is also an option to take SCSEMBLIX 40 mg tablets twice a day (AM + PM)

Patients should:



Avoid food consumption for at least 2 hours before and 1 hour after taking SCSEMBLIX¹



Swallow SCSEMBLIX whole—do not break, crush, or chew them¹



SCSEMBLIX is available as film-coated tablets: **20 mg** (6.2 mm diameter) and **40 mg** (8.2 mm diameter)¹

Based on pharmacokinetic parameters studied in an exposure-response analysis, the predicted efficacy and safety profile of SCSEMBLIX at the 80 mg qd dose is similar to that at the 40 mg bid dose.⁵

Dosage reductions

For the management of adverse reactions, reduce the SCSEMBLIX dose as described in the table below

Recommended dosage reductions for SCSEMBLIX for adverse reactions¹

Dosage reduction	Dosage for patients with Ph+ CML-CP previously treated with ≥2 TKIs
First reduction	<ul style="list-style-type: none"> • 40 mg qd OR • 20 mg bid
Subsequent reduction	Permanently discontinue SCSEMBLIX in patients unable to tolerate 40 mg qd OR 20 mg bid

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

Dosage modifications for the management of adverse reactions

Dose modifications for the management of adverse reactions¹

Adverse reaction	Dosage modification
Thrombocytopenia and/or neutropenia	
ANC less than $1.0 \times 10^9/L$ and/or PLT less than $50 \times 10^9/L$	Withhold SCSEMBLIX until resolved to ANC greater than or equal to $1 \times 10^9/L$ and/or PLT greater than or equal to $50 \times 10^9/L$. If resolved: <ul style="list-style-type: none"> • Within 2 weeks: Resume SCSEMBLIX at starting dose • After more than 2 weeks: Resume SCSEMBLIX at reduced dose For recurrent severe thrombocytopenia and/or neutropenia, withhold SCSEMBLIX until resolved to ANC greater than or equal to $1 \times 10^9/L$ and PLT greater than or equal to $50 \times 10^9/L$, then resume at reduced dose.
Asymptomatic amylase and/or lipase elevation	
Elevation greater than $2.0 \times ULN$	Withhold SCSEMBLIX until resolved to less than $1.5 \times ULN$. <ul style="list-style-type: none"> • If resolved, resume SCSEMBLIX at reduced dose. If events reoccur at reduced dose, permanently discontinue SCSEMBLIX • If not resolved, permanently discontinue SCSEMBLIX. Perform diagnostic tests to exclude pancreatitis
Nonhematologic adverse reactions	
Grade 3 ^a or higher	Withhold SCSEMBLIX until recovery to Grade 1 or less. <ul style="list-style-type: none"> • If resolved, resume SCSEMBLIX at reduced dose • If not resolved, permanently discontinue SCSEMBLIX

ANC, absolute neutrophil count; PLT, platelets; ULN, upper limit of normal.
^aBased on Common Terminology Criteria for Adverse Events (CTCAE) v4.03.

Please refer to the full Prescribing Information for dose reduction, modification, and discontinuation of SCSEMBLIX in the event of specific adverse reactions. Management of dosing for each patient should be based on individual benefit/risk assessment.

IMPORTANT SAFETY INFORMATION for SCSEMBLIX (cont)

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

Patient counseling¹

Advise patients taking SCEMBLIX to report any signs or symptoms of potential treatment-related adverse reactions. In addition, advise patients to read the FDA-approved patient labeling (Patient Information).

Myelosuppression	Inform patients of the possibility of developing low blood cell counts. Advise patients to immediately report fever, any suggestion of infection, or signs or symptoms suggestive of bleeding or easy bruising.
Pancreatic Toxicity	Inform patients of the possibility of developing pancreatitis that may be accompanied by nausea, vomiting, severe abdominal pain, or abdominal discomfort, and to promptly report these symptoms.
Hypertension	Inform patients of the possibility of developing hypertension. Advise patients to contact their health care provider for elevated blood pressure or if symptoms of hypertension occur, including confusion, headache, dizziness, chest pain, or shortness of breath.
Hypersensitivity	Advise the patient to discontinue SCEMBLIX and seek immediate medical attention if any signs or symptoms of a hypersensitivity reaction, such as rash, edema, or bronchospasm occur.
Cardiovascular Toxicity	Inform patients of the possibility of the occurrence of cardiovascular toxicity, especially those with a history of cardiovascular risk factors. Advise patients to immediately contact their health care provider or get medical help if they develop cardiovascular signs and symptoms.
Embryo-Fetal Toxicity	Advise women to inform their health care provider if they are pregnant or become pregnant. Inform female patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 week after receiving the last dose of SCEMBLIX.
Lactation	Advise women not to breastfeed during treatment with SCEMBLIX and for at least 1 week after the last dose.
Infertility	Advise women of reproductive potential of the potential for impaired fertility from SCEMBLIX.
Drug Interactions	Advise patients that SCEMBLIX and certain other medicines, including over the counter medications or herbal supplements, can interact with each other and may alter the effects of SCEMBLIX.

Drug interactions¹

Effect of Other Drugs on SCEMBLIX

Strong CYP3A4 Inhibitors

- Asciminib is a CYP3A4 substrate. Concomitant use of SCEMBLIX with a strong CYP3A4 inhibitor increases both the asciminib C_{max} and AUC, which may increase the risk of adverse reactions
- Closely monitor for adverse reactions in patients treated with SCEMBLIX at 200 mg bid with concomitant use of strong CYP3A4 inhibitors

Itraconazole Oral Solution Containing Hydroxypropyl- β -cyclodextrin

- Concomitant use of SCEMBLIX with itraconazole oral solution containing hydroxypropyl- β -cyclodextrin decreases asciminib C_{max} and AUC, which may reduce SCEMBLIX efficacy
- Avoid coadministration of SCEMBLIX at all recommended doses with itraconazole oral solution containing hydroxypropyl- β -cyclodextrin

Effect of SCEMBLIX on Other Drugs

Certain CYP3A4 Substrates

- Asciminib is a CYP3A4 inhibitor. Concomitant use of SCEMBLIX increases the C_{max} and AUC of CYP3A4 substrates, which may increase the risk of adverse reactions of these substrates
- Closely monitor for adverse reactions in patients treated with SCEMBLIX at 80 mg total daily dose with concomitant use of certain CYP3A4 substrates, where minimal concentration changes may lead to serious adverse reactions
- Avoid coadministration of SCEMBLIX at 200 mg bid with certain CYP3A4 substrates, where minimal concentration changes may lead to serious adverse reactions

CYP2C9 Substrates

- Asciminib is a CYP2C9 inhibitor. Concomitant use of SCEMBLIX increases the C_{max} and AUC of CYP2C9 substrates, which may increase the risk of adverse reactions of these substrates
- Avoid coadministration of SCEMBLIX at 80 mg total daily dose with certain CYP2C9 substrates, where minimal concentration changes may lead to serious adverse reactions. If coadministration is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information
- Avoid coadministration of SCEMBLIX at 200 mg bid with sensitive CYP2C9 substrates and certain CYP2C9 substrates, where minimal concentration changes may lead to serious adverse reactions. If coadministration is unavoidable, consider alternative therapy with non-CYP2C9 substrate

Certain P-gp Substrates

- Asciminib is a P-gp inhibitor. Concomitant use of SCEMBLIX increases the plasma concentrations of P-gp substrates, which may increase the risk of adverse reactions of these substrates
- Closely monitor for adverse reactions in patients treated with SCEMBLIX at all recommended doses with concomitant use of P-gp substrates, where minimal concentration changes may lead to serious toxicities

Substrates of OATP1B or BCRP

- Asciminib is an OATP1B and BCRP inhibitor. The effect of concomitant use of SCEMBLIX with OATP1B and BCRP substrates has not been established in clinical studies. However, based upon a mechanistic understanding of the elimination of asciminib and its in vitro inhibitory potential, concomitant use of SCEMBLIX increases the C_{max} and AUC of OATP1B and BCRP substrates, which may increase the risk of adverse reactions of these substrates
- Avoid coadministration of SCEMBLIX at all recommended doses with rosuvastatin and atorvastatin. Closely monitor for adverse reactions in patients treated with SCEMBLIX at all recommended doses with concomitant use of other OATP1B or BCRP substrates. Reduce the dosage of the other OATP1B or BCRP substrates as recommended in their Prescribing Information when used concomitantly with SCEMBLIX at all recommended doses

IMPORTANT SAFETY INFORMATION FOR SCEMBLIX

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 asymptomatic 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 3 fatalities were reported
- 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- 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 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.

References: **1.** Scemblix. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Hochhaus A, Réa D, Boquimpani C, et al. *Leukemia*. 2023;37(3):617-626. **3.** Data on file. CABL001A2301 clinical study report. Novartis Pharmaceuticals Corp; 2022. **4.** Réa D, Mauro MJ, Boquimpani C, et al. *Blood*. 2021;138(21):2031-2041. **5.** Combes FP, Li YF, Hoch M, Lorenzo S, Ho Y-Y, Sy SKB. *Clin Pharmacol Ther*. 2022;112(5):1040-1050.

SCEMBLIX: FOR ADULTS WITH Ph+ CML-CP PREVIOUSLY TREATED WITH 2 TKIs

A once-daily dosing option to accommodate your patients¹

Patients previously treated with ≥ 2 TKIs:

80 mg once daily

There is also an option to take SCEMBLIX 40 mg tablets twice a day (AM + PM)

Patients should:



Avoid food consumption for at least 2 hours before and 1 hour after taking SCEMBLIX¹



Swallow SCEMBLIX whole—do not break, crush, or chew them¹



SCEMBLIX is available as film-coated tablets: **20 mg** (6.2 mm diameter) and **40 mg** (8.2 mm diameter)¹

Based on pharmacokinetic parameters studied in an exposure-response analysis, the predicted efficacy and safety profile of SCEMBLIX at the 80 mg qd dose is similar to that at the 40 mg bid dose.⁵

Warning and Precautions for SCEMBLIX include myelosuppression, pancreatic toxicity, hypertension, hypersensitivity, cardiovascular toxicity, and embryo-fetal toxicity. The most common adverse reactions ($\geq 20\%$) were upper respiratory tract infections, musculoskeletal pain, headache, fatigue, nausea, rash, and diarrhea.

Discover SCEMBLIX at scemblix-hcp.com

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



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 **SCEMBLIX**[®]
(asciminib) 20 mg, 40 mg tablets