

Patient portraits

Do your patients with Ph+ CML-CP need a different approach?

Learn how SCEMBLIX can help appropriate patients with Ph+ CML-CP previously treated with 2 TKIs.¹

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)

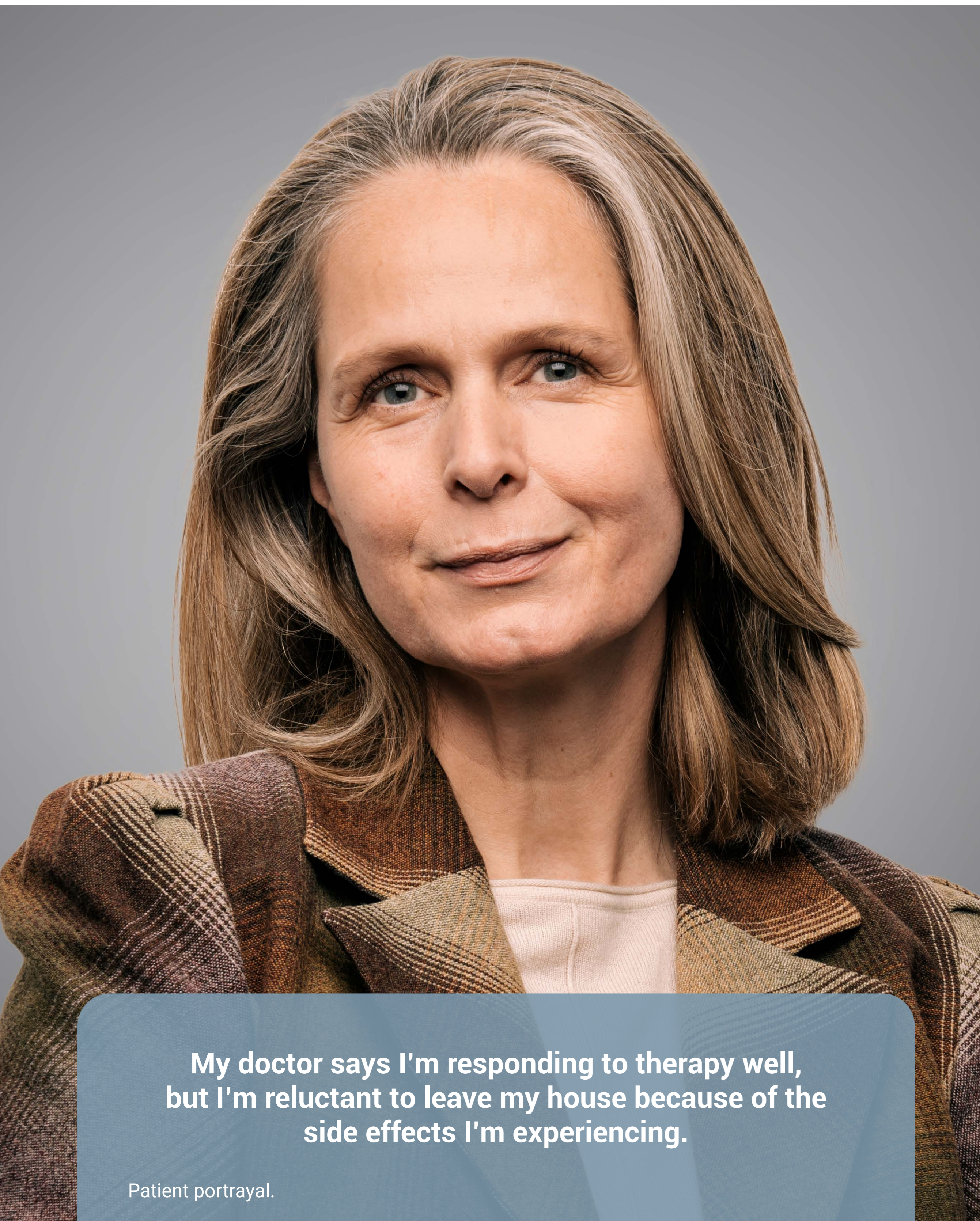
IMPORTANT SAFETY INFORMATION for SCEMBLIX

Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).

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



My doctor says I'm responding to therapy well, but I'm reluctant to leave my house because of the side effects I'm experiencing.

Patient portrayal.

What's your next move for a patient experiencing moderate and persistent* GI ARs on their 2nd TKI?

Clinical Presentation and Medical History

- 70 years old
- Diagnosed 2 years ago with Ph+ CML-CP
- Active dyslipidemia managed with a medication
- After ~5 months on her 1st TKI, she switched treatments due to grade 3 edema
- After 1 year on her 2nd TKI, she is experiencing grade 2 GI adverse reactions (diarrhea, nausea)
- **Quantitative RT-PCR (qPCR) using IS for *BCR::ABL1* (blood): ≤0.1%**

Ramona's Story

Ramona retired about a year ago after a long career in real estate, which happened to coincide with starting a 2nd TKI. She has 6 grandchildren who live nearby and has become somewhat of a local legend at pickleball.

Her first year of retirement has been wonderful, but recently she has developed moderate and persistent* GI ARs (diarrhea and nausea). Her doctor told her it's just part of treatment, but she thinks twice now before taking her grandchildren off on an adventure, and she hasn't been showing up at the courts as much.

Her Latest Visit

Ramona is responding well to her 2nd TKI. However, when her doctor asked her how she has been doing, Ramona shared that she has been much less active than normal. She said that she was concerned about leaving her house due to the diarrhea and nausea she has been experiencing during the last few months. She has tried over-the-counter medications to alleviate some of her symptoms, but they do not seem to be helping. Her doctor has also tried dose adjustment.

Review the tolerability profile for SCEMBLIX and learn how it might benefit patients like Ramona.¹



AR, adverse reaction; GI, gastrointestinal; IS, International Scale; Ph+ CML-CP, Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase; RT-PCR, reverse transcription polymerase chain reaction; TKI, tyrosine kinase inhibitor.

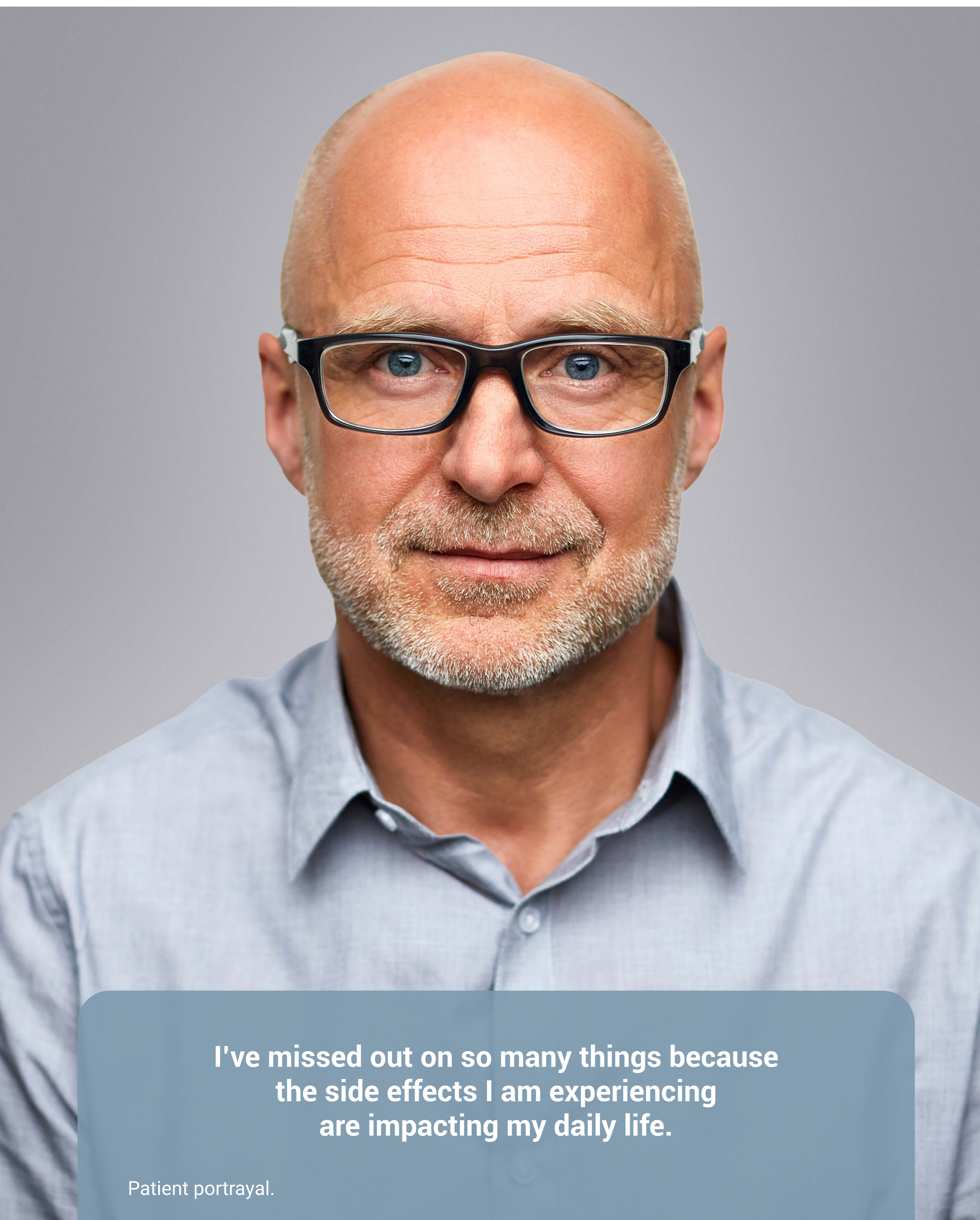
*Grade 2 toxicity that is unresponsive to optimal management, including dose adjustments.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (cont)

Myelosuppression (cont)

- 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

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).



I've missed out on so many things because the side effects I am experiencing are impacting my daily life.

Patient portrayal.

How would you treat a patient who is experiencing early intolerance on their 2nd TKI?

Clinical Presentation and Medical History

- 50 years old
- Diagnosed 6 years ago with Ph+ CML-CP
- Comorbidities include diabetes managed with insulin
- After ~5.5 years on his 1st TKI, he switched treatments due to loss of response
- After 3 months on his 2nd TKI, he began experiencing a bothersome grade 3 rash and increased ALT/AST (signaling early intolerance), which had not resolved 4 months later
- **Quantitative RT-PCR (qPCR) using IS for *BCR::ABL1* (blood): 7%**

Brooks' Story

Brooks is married, the father of 3 children, and best friend to the family dog. He enjoys being an active member of the community and has a financial planning practice with an office downtown.

Recently, he started a different Ph+ CML-CP treatment and has developed increased ALT and AST, as well as a bothersome grade 3 rash. As a result, he has withdrawn somewhat from his usual community activities and spends less time in town with his family.

His Latest Visit

His doctor said that while they understood Brooks had a rash, he was responding well to treatment. Brooks told his doctor the rash made it hard to meet with clients.

See what the tolerability and safety profile of SCEMBLIX can mean for patients experiencing intolerance on their 2nd TKI.¹



ALT, alanine transaminase; AST, aspartate aminotransferase; IS, International Scale; Ph+ CML-CP, Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase; RT-PCR, reverse transcription polymerase chain reaction; TKI, tyrosine kinase inhibitor.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (cont)

Myelosuppression (cont)

- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

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In CML, the focus is usually on living longer, but the side effects I'm experiencing make my daily life harder.

Patient portrayal.

How would you treat a patient who is experiencing moderate and persistent* ARs on their 2nd TKI?

Clinical Presentation and Medical History

- 63 years old
- Diagnosed 8 years ago with Ph+ CML-CP
- History of controlled anxiety
- After ~7 years on her 1st TKI, she switched treatments due to an adverse reaction (grade 2 fatigue)
- After 1 year on her 2nd TKI, she is experiencing fatigue and diarrhea (both grade 2)
- Her doctor told her to try an OTC medicine for her diarrhea, but it didn't help. Dose adjustment also did not help
- **Quantitative RT-PCR (qPCR) using IS for *BCR::ABL1* (blood): <0.1%**

Maria's Story

Maria is a grandmother of 2, a nurse, and a golfer—all of which keep her on her feet. She switched to her 2nd TKI about 1 year ago because of fatigue, but now she once again finds herself experiencing fatigue and diarrhea.

She's no longer comfortable being out on the golf course or having her grandchildren visit on their own, and she has started to take fewer shifts at the hospital.

Her Latest Visit

Maria told her doctor she was doing some research online and read somewhere that she might be able to take her medicine every other day instead of every day. She asked if doing that might affect how well her medicine is working.

Learn about the efficacy and tolerability profile of SCEMBLIX and see what it can mean for patients like Maria.¹



AR, adverse reaction; CCyR, complete cytogenetic response; IS, International Scale; OTC, over the counter; Ph+ CML-CP, Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase; RT-PCR, reverse transcription polymerase chain reaction; TKI, tyrosine kinase inhibitor.

*Grade 2 toxicity that is unresponsive to optimal management, including dose adjustments.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (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 SCEMBLIX

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).



I'm not a complainer, and I don't want to bother anybody, so I just deal with treatment side effects myself.

Patient portrayal.

What would be the next step for a patient with a suboptimal response on their 2nd TKI?

Clinical Presentation and Medical History

- 42 years old
- Diagnosed 3 years ago with Ph+ CML-CP
- After 4 years on his 1st TKI, he switched treatments due to loss of response
- After 6 months on his 2nd TKI, his *BCR::ABL1* transcript levels are still greater than 10% (signaling a lack of response)
- **Quantitative RT-PCR (qPCR) using IS for *BCR::ABL1* (blood): 10.1%**
- Patient underwent a mutational analysis; no resistant mutation was identified

Jim's Story

Jim is a physical therapist, a runner, and the coach of his 12-year-old son's soccer team. He began treatment for Ph+ CML-CP a few years ago but had to switch treatments due to a loss of response.

Now on his 2nd TKI, he is facing another possible loss of response.

His Latest Visit

Jim's doctor suspected an issue and asked him if he was experiencing any side effects that impacted his daily life.

See if the response rates of SCEMBLIX can help patients like Jim get back on track.¹



IS, International Scale; Ph+ CML-CP, Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase; RT-PCR, reverse transcription polymerase chain reaction; TKI, tyrosine kinase inhibitor.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (cont)

Pancreatic Toxicity (cont)

- 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

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).

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(asciminib) 20 mg, 40 mg tablets



How would you help a patient with a suboptimal response on their 2nd TKI?

Clinical Presentation and Medical History

- 51 years old
- Diagnosed with Ph+ CML-CP 5 years ago
- Occasional GERD treated with a PPI
- After 4 years on his 1st TKI, he switched treatments due to loss of response
- After 1 year on his 2nd TKI, he has not achieved CCyR (signaling a suboptimal response)
- **Quantitative RT-PCR (qPCR) using IS for *BCR::ABL1* (blood): 5%**
- Patient underwent a mutational analysis; no resistant mutation was identified

Apollo's Story

Apollo is a high-school English teacher. He lives with his partner and 2 sons and leads a book club that meets at the library. He was on his 1st TKI for 4 years before experiencing a loss of response. The same thing happened on his 2nd TKI, but after only 1 year.

His Latest Visit

Apollo expressed frustration and considerable anxiety about being unable to achieve an adequate response to treatment.

Learn more about the proven efficacy of SCEMBLIX to see what's possible for patients like Apollo.¹



CCyR, complete cytogenetic response; GERD, gastroesophageal reflux disease; IS, International Scale; Ph+ CML-CP, Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase; PPI, proton-pump inhibitor; RT-PCR, reverse transcription polymerase chain reaction; TKI, tyrosine kinase inhibitor.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (cont)

Pancreatic Toxicity (cont)

- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis

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IMPORTANT SAFETY INFORMATION FOR SCEMBLIX**INDICATION**

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- 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

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

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).

IMPORTANT SAFETY INFORMATION FOR SCEMBLIX (cont)

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 see full [Prescribing Information](#).

Reference: 1. Scemblix. Prescribing information. Novartis Pharmaceuticals Corp.

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