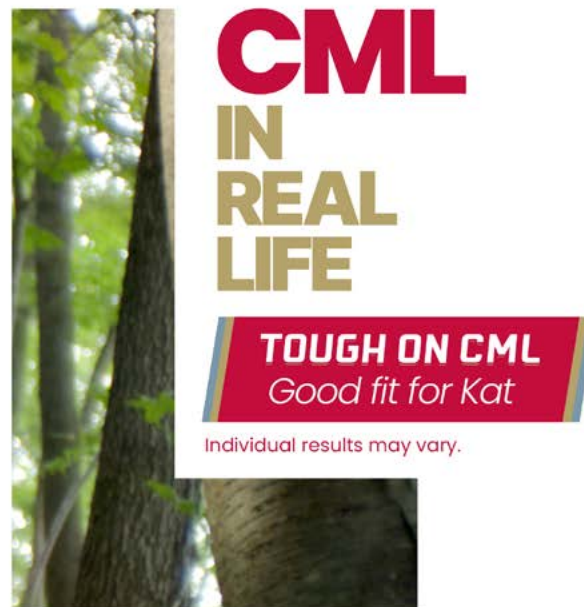


FOR ADULTS WITH NEWLY DIAGNOSED OR PREVIOUSLY TREATED Ph+ CML-CP



Kat | Real patient

SCEMBLIX IS A TARGETED, ORAL THERAPY THAT WORKS DIFFERENTLY—

it's the only TKI that is thought to bind to a different site (myristoyl pocket) within the abnormal protein that causes Ph+ CML-CP

Ph+ CML-CP, Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase; TKI, tyrosine kinase inhibitor.

APPROVED USES

SCEMBLIX is a prescription medicine used to treat adults with:

- Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
 - The approval of SCEMBLIX in patients newly diagnosed is based on a study that measured major molecular response (MMR) rate. There are ongoing studies to confirm the clinical benefit of SCEMBLIX for this use and how SCEMBLIX works over a longer period of time
- Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15.

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

**AL ENJOYS
WORKING WITH
ROBOTICS AND
GARDENING.**

Al
Real patient

IMPORTANT SAFETY INFORMATION (continued)

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you: (continued)

Females who are able to become pregnant:

- Your doctor will do a pregnancy test before you start treatment with SCEMBLIX
- You should use effective birth control (contraception) during treatment and for 1 week after your last dose of SCEMBLIX. Talk to your doctor about birth control methods that may be right for you
- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SCEMBLIX
- are breastfeeding or plan to breastfeed. It is not known if SCEMBLIX passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of SCEMBLIX

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

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15. 2

FOR MANY, A DIAGNOSIS OF Ph+ CML-CP IS UNEXPECTED

Ph+ CML in chronic phase can often be diagnosed during a routine physical examination or after blood tests. It's important to take an active role in your treatment decisions from the start, so be sure to have ongoing talks with your doctor to determine which medication may be right for you.



What is Ph+ CML in chronic phase?

Ph+ CML is a blood and bone marrow cancer (bone marrow is a tissue that creates blood cells). Ph+ CML occurs in the body when 2 chromosomes fuse abnormally. This creates a new, atypical chromosome: the Philadelphia (Ph) chromosome.

The Ph chromosome creates the abnormal *BCR::ABL1* fusion gene, which generates an abnormal protein, BCR-ABL. This protein causes uncontrolled growth of abnormal white blood cells, also known as leukemic cells.

There are 3 phases of Ph+ CML. Chronic phase is the first phase of Ph+ CML. Most adults are diagnosed in chronic phase.

Work with your doctor to find a treatment that suits you

Tyrosine kinase inhibitors (TKIs) are a type of medication approved to treat Ph+ CML. TKIs can be prescribed to those newly diagnosed with Ph+ CML-CP, or if your doctor decides to switch you to a different TKI because treatment milestones were not reached or it caused unmanageable side effects.

Ask your doctor about SCEMBLIX.


IMPORTANT SAFETY INFORMATION (continued)

Tell your doctor about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

Taking SCEMBLIX with certain other medicines may affect each other causing side effects and may affect the way that SCEMBLIX works.

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

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15. **3**



Kat
Real patient

**KAT ENJOYS PLAYING
THE PIANO AND
WALKING IN NATURE.**

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including:

- **Low blood cell counts:** SCEMBLIX may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your doctor will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with SCEMBLIX. Tell your doctor right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection

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

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15.

SCEMBLIX TARGETS THE ABNORMAL PROTEIN THAT CAUSES Ph+ CML-CP DIFFERENTLY

SCEMBLIX is thought to work by binding to a different site (myristoyl pocket) to help block the activity of the abnormal protein that causes Ph+ CML-CP

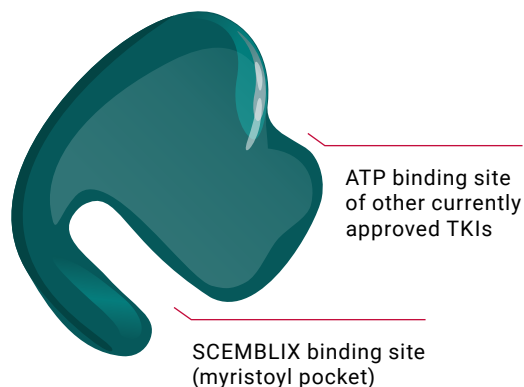
Ph+ CML is caused by a continuously active abnormal protein (BCR-ABL) that leads to uncontrolled growth of abnormal white blood cells.

All other currently approved TKIs bind to this abnormal protein at a site known as the ATP binding site to help block the protein's activity.

SCEMBLIX targets a different site of this abnormal protein to help block the protein's activity.

BCR-ABL abnormal protein

BCR-ABL leads to uncontrolled growth of abnormal white blood cells in Ph+ CML-CP.



SCEMBLIX in action

SCEMBLIX helps block the activity of BCR-ABL by binding to a different site.



SCEMBLIX is the only treatment that is thought to bind to a different site to help block the activity of the abnormal protein that causes Ph+ CML-CP.

ATP, adenosine triphosphate.

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including: (continued)

- **Pancreas problems:** SCEMBLIX may increase enzymes in your blood called amylase and lipase, which may be a sign of inflammation of the pancreas (pancreatitis). Your doctor may do blood tests monthly or as needed during treatment with SCEMBLIX to check for problems with your pancreas. Tell your doctor right away if you have severe stomach-area (abdominal) pain or discomfort, nausea, or vomiting

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

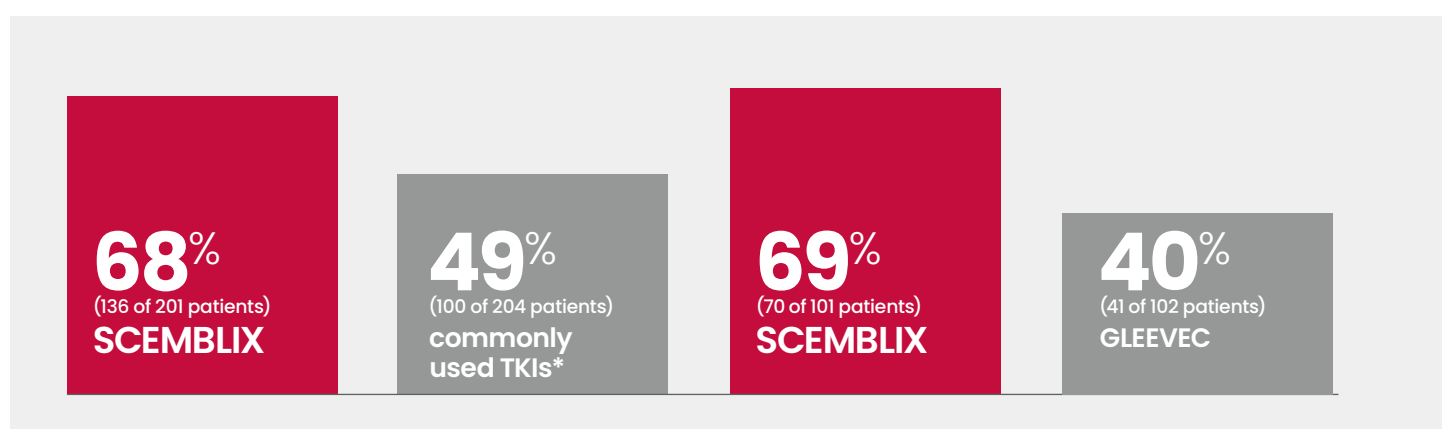
Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15. 5

In a head-to-head clinical study of adults with newly diagnosed Ph+ CML-CP

MORE PEOPLE ACHIEVED MMR WITH SCEMBLIX THAN WITH COMMONLY USED TKIs* AT NEARLY 1 YEAR (48 WEEKS)

Major molecular response (MMR) is an important milestone in the treatment of Ph+ CML in chronic phase.

SCEMBLIX is the only medication that went head-to-head against all the most commonly used TKIs* for newly diagnosed patients. SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). To learn more about this study, visit www.scemblix.com



*Ask your doctor to consider
SCEMBLIX for your first treatment.*

*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including: (continued)

- **High blood pressure:** Your doctor may check your blood pressure and treat any high blood pressure during treatment with SCEMBLIX as needed. Tell your doctor if you develop high blood pressure or symptoms of high blood pressure including confusion, headaches, dizziness, chest pain, or shortness of breath

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

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15. **6**

SCEMBLIX WORKED FAST

The time by which half of the patients in each study arm achieved MMR:

(SCEMBLIX study arm: 201 patients, commonly used-TKIs study arm: 204 patients)

24 weeks with SCEMBLIX

36 weeks with commonly used TKIs*

*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib).
Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

AI
Real patient

**AL WAS DIAGNOSED
WITH Ph+ CML IN
1997 AND HAS TRIED
MULTIPLE TKIs.**

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including: (continued)

- **Allergic reaction:** Stop taking SCEMBLIX and get medical help right away if you get any signs or symptoms of an allergic reaction, including:
 - trouble breathing or swallowing
 - swelling of the face, lips, or tongue
 - skin rash or flushing of your skin
 - feeling dizzy or faint
 - fever
 - fast heartbeat

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

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15. 7



**KAT WAS
DIAGNOSED WITH
Ph+ CML AT AGE 19
AND HAS TRIED
MULTIPLE TKIs.**

Kat
Real patient

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including: (continued)

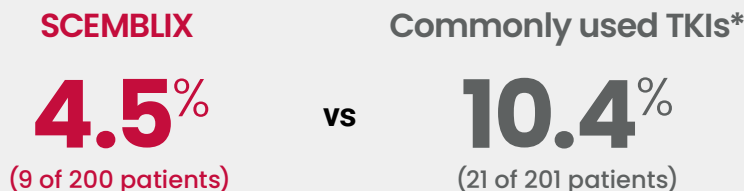
- **Heart and blood vessel (cardiovascular) problems:** SCEMBLIX may cause heart and blood vessel problems, including heart attack, stroke, blood clots or blockage of your arteries, heart failure, and abnormal heartbeat, which can be serious and may sometimes lead to death. In the majority of cases, these heart and blood vessel problems happened in people with risk factors or a history of these problems, and previously treated with other tyrosine kinase inhibitor (TKI) medicines. Your doctor may monitor you for heart and blood vessel problems and treat you as needed during treatment with SCEMBLIX. Tell your doctor or get medical help right away if you get:
 - shortness of breath
 - chest pain or pressure
 - a feeling like your heart is beating too fast or you feel abnormal heartbeats
 - swelling in your ankles or feet
 - dizziness
 - weight gain
 - numbness or weakness on one side of your body
 - decreased vision or loss of vision
 - trouble talking
 - pain in your arms, legs, back, neck, or jaw
 - headache
 - severe stomach-area (abdominal) pain

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

In a head-to-head clinical study of adults with newly diagnosed Ph+ CML-CP

MORE PEOPLE WERE ABLE TO STAY ON SCEMBLIX FOR 48 WEEKS

Patients who had to stop treatment specifically due to side effects at nearly 1 year (48 weeks):



By 48 weeks, 90% of patients on SCEMBLIX were still on treatment vs 81% of patients on the most commonly used TKIs.*

*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

COMMON SIDE EFFECTS

In this clinical study, the most common side effects reported ($\geq 10\%$) with SCEMBLIX were pain in the muscles, bones, or joints; rash; fatigue; diarrhea; abdominal pain; nose, throat, or sinus infections; increased triglycerides and cholesterol levels; and headache.

These are not all of the possible side effects of SCEMBLIX. Call your doctor for medical advice about side effects.

Everyone responds differently to treatment.
It's important to discuss the potential side effects of each treatment you and your doctor are considering.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of SCEMBLIX include:

- muscle, bone, or joint pain
- rash
- tiredness
- nose, throat, or sinus (upper respiratory tract) infections
- headache
- stomach-area (abdominal) pain
- diarrhea
- decreased white blood cell counts, platelet counts, and red blood cell counts
- decreased blood calcium corrected levels
- increased blood pancreas enzyme (lipase and amylase) levels
- increased blood fat (cholesterol and triglycerides) levels
- increased blood uric acid levels
- increased blood liver enzyme levels
- increased blood alkaline phosphatase levels
- increased blood creatine kinase levels

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

Please see Important Safety Information throughout and the [Summary of Important Information on pages 14–15.](#) **9**

ORAL TABLETS, DAILY DOSING

Once you start SCEMBLIX, it's important to take your medication exactly as prescribed by your doctor. Also, be sure to keep up with blood tests so your doctor can see how you're responding to treatment.

Kat
Real patient



Important things about your daily SCEMBLIX routine



It's important to **take SCEMBLIX at the same time every day**. **Don't stop taking SCEMBLIX or change your dose or schedule** unless directed by your doctor.



SCEMBLIX comes in 20 mg, 40 mg, and 100 mg oral tablets. Your doctor will discuss with you how many times a day to take SCEMBLIX.



Do NOT take SCEMBLIX with food. Avoid eating for at least 2 hours before and 1 hour after you take SCEMBLIX.



Swallow SCEMBLIX tablets whole. Don't break, crush, or chew SCEMBLIX tablets.



If you miss a dose:

If you take SCEMBLIX **once a day** and miss a dose by more than 12 hours, skip the missed dose and take your next dose at your regular time.



If you take SCEMBLIX **twice a day** and miss a dose by more than 6 hours, skip the missed dose and take your next dose at your regular time.

IMPORTANT SAFETY INFORMATION (continued)

Your doctor may change your dose, temporarily stop, or permanently stop treatment with SCEMBLIX if you have certain side effects.

SCEMBLIX may cause fertility problems in females. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

These are not all the possible side effects of SCEMBLIX. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

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

Please see Important Safety Information throughout and the [Summary of Important Information on pages 14–15](#). **10**

QUESTIONS FOR YOUR DOCTOR TO SEE IF SCEMBLIX MAY BE RIGHT FOR YOU

Whether you're newly diagnosed with Ph+ CML in chronic phase or already taking another CML medication, it's important to take an active role in your treatment. Use this guide to discuss with your doctor if SCEMBLIX may be right for you.



Questions to ask your doctor:

1. How is SCEMBLIX different from other medications that treat Ph+ CML-CP?
2. When might I expect to see results with SCEMBLIX?
3. What are the most serious and common side effects of SCEMBLIX?
4. How will I know if SCEMBLIX is working?
5. What are some treatment milestones I should know about?
6. What are the results of my latest blood work?



Are you experiencing side effects from your current treatment for Ph+ CML-CP? Tell your doctor.

Below are some side effects that may occur during treatment for Ph+ CML-CP. Check any that apply.

- | | |
|--|---|
| <input type="checkbox"/> Diarrhea | <input type="checkbox"/> Bone, muscle, and joint pain |
| <input type="checkbox"/> Nausea/vomiting | <input type="checkbox"/> Something else: _____ |
| <input type="checkbox"/> Rash/itching | _____ |

Ph+ CML medications can cause other side effects, so discuss any side effects you're experiencing with your doctor.



Scan the code for a more in-depth guide
for talking with your doctor about SCEMBLIX.

IMPORTANT SAFETY INFORMATION (continued)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, including Patient Information.

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

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15. **11**

NOVARTIS PATIENT SUPPORT™

PERSONALIZED SUPPORT TO HELP YOU START, STAY, AND SAVE ON SCEMBLIX

Once you've been prescribed SCEMBLIX, you or your loved one can sign up for Novartis Patient Support. You'll have a go-to team member who will reach out from the start and get to know you. And once your health care provider has filed the paperwork with your insurance, Novartis Patient Support can help with the rest.

FINANCIAL SUPPORT

How can I save on SCEMBLIX?

Cost shouldn't be a barrier between you and the treatment you need. Your support will be based on your unique financial situation. This includes things like your prescription and insurance coverage. Novartis Patient Support offers options to help you afford your treatment.



What is Co-Pay Plus?

The Co-Pay Plus offer can help cover out-of-pocket costs related to your SCEMBLIX prescription, including refills. If you have private insurance, you may be eligible.

\$0 Co-Pay Plus* offer

Pay as little as \$0 with your Co-Pay Plus offer.

- Eligible patients with private insurance may pay as little as \$0
- Have an annual benefit limit of \$15,000 per calendar year
- Your annual benefit limit automatically resets every year, provided you continue to be eligible. There's no need to sign up again



30-day Free Trial Offer for SCEMBLIX†

Your Free Trial Offer for SCEMBLIX is good for a 30-day supply of your medication at no cost to you. This offer is available to all with a valid prescription‡—regardless of insurance. For one-time use only.

NOVARTIS PATIENT ASSISTANCE FOUNDATION SUPPORT

Novartis Patient Assistance Foundation, Inc. (NPAF), an independent 501(c)(3) non-profit organization, provides Novartis medications free of cost to eligible patients who have limited or no prescription insurance coverage and cannot afford the cost of their medication.

To be eligible, you must:

- Reside in the United States or a US territory
- Be treated by a licensed US health care provider on an outpatient basis
- Meet income and insurance guidelines

Visit www.PAP.Novartis.com or call NPAF at 1-800-277-2254 to learn more about eligibility and how to apply.



INSURANCE SUPPORT

How can my Novartis Patient Support team help me navigate insurance coverage?

Getting you the medication you need is our number one priority. Novartis Patient Support is here to help. You'll work with an experienced team member who can:

- Help you navigate the insurance process
- Provide information to your health care provider to assist them with your insurance needs
- Assist you if there are changes to your insurance coverage

***Limitations apply.** Valid only for those with private insurance. The Program includes the Co-Pay Plus offer, Plus Card (if applicable), and Rebate, with a combined annual limit up to \$15,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

***No purchase required.** This free trial is not health insurance. Void where prohibited by law. Valid only in the US and Puerto Rico. Claims shall not be submitted to any public or private third-party payer or any federal or state health care program for reimbursement. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this offer without notice. Additional limitations apply. See full Terms & Conditions for details.

†Confirm your specialty pharmacy accepts this offer before filling your prescription.

ONGOING SUPPORT

Once you've started treatment, your Novartis Patient Support team will be there for you.

Live, one-on-one support is just a phone call away for:

- Guidance on your health plan coverage process
- Options for saving on your prescription
- Setting up your routine and getting more help with SCEMBLIX
- Educational resources about SCEMBLIX and living with Ph+ CML in CP and Ph+ CML in CP with the T315I mutation
- Your choice of texts, calls, and emails to keep you connected to ongoing support

Novartis Patient Support doesn't replace medical guidance from your health care provider. Our goal is to help you feel informed about your treatment from day one.

How do I sign up for Novartis Patient Support?

Once your health care provider prescribes SCEMBLIX, there are 3 ways you can sign up for Co-Pay Plus and Novartis Patient Support:



Online

Enter your information securely online at support.scemblix.com



Call 866-433-8000

Monday–Friday, 8 AM to 8 PM ET, excluding holidays. Your dedicated Novartis Patient Support team can then help you sign up.



Ask your provider

Your health care provider and/or their office staff can help you sign up.

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

SUMMARY OF IMPORTANT INFORMATION FOR SCEMBLIX

What is SCEMBLIX?

SCEMBLIX is a prescription medicine used to treat adults with:

- Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
- The approval of SCEMBLIX in patients newly diagnosed is based on a study that measured major molecular response (MMR) rate. There are ongoing studies to confirm the clinical benefit of SCEMBLIX for this use and how SCEMBLIX works over a longer period of time
- Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby

Females who are able to become pregnant:

- Your doctor will do a pregnancy test before you start treatment with SCEMBLIX
- You should use effective birth control (contraception) during treatment and for 1 week after your last dose of SCEMBLIX. Talk to your doctor about birth control methods that may be right for you
- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SCEMBLIX
- are breastfeeding or plan to breastfeed. It is not known if SCEMBLIX passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of SCEMBLIX

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking SCEMBLIX with certain other medicines may affect each other causing side effects and may affect the way that SCEMBLIX works.

How should I take SCEMBLIX?

- Take SCEMBLIX exactly as your doctor tells you to take it
- **Do not** change your dose or schedule or stop taking SCEMBLIX unless your doctor tells you to
- Take SCEMBLIX without food. **You should avoid eating** for at least 2 hours before and 1 hour after taking SCEMBLIX
- Swallow SCEMBLIX tablets whole. **Do not break**, crush, or chew SCEMBLIX tablets
- If you take SCEMBLIX **1 time a day** and miss a dose by more than 12 hours, skip the missed dose and take your next dose at your regular time
- If you take SCEMBLIX **2 times a day** and miss a dose by more than 6 hours, skip the missed dose and take your next dose at your regular time

What are the possible side effects of SCEMBLIX?

SCEMBLIX may cause serious side effects, including:

- **Low blood cell counts:** SCEMBLIX may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your doctor will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with SCEMBLIX. Tell your doctor right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection
- **Pancreas problems:** SCEMBLIX may increase enzymes in your blood called amylase and lipase, which may be a sign of inflammation of the pancreas (pancreatitis). Your doctor may do blood tests monthly or as needed during treatment with SCEMBLIX to check for problems with your pancreas. Tell your doctor right away if you have severe stomach-area (abdominal) pain or discomfort, nausea, or vomiting
- **High blood pressure:** Your doctor may check your blood pressure and treat any high blood pressure during treatment with SCEMBLIX as needed. Tell your doctor if you develop high blood pressure or symptoms of high blood pressure including confusion, headaches, dizziness, chest pain, or shortness of breath

SUMMARY OF IMPORTANT INFORMATION FOR SCEMBLIX (cont)

- **Allergic reaction:** Stop taking SCEMBLIX and get medical help right away if you get any signs or symptoms of an allergic reaction, including:

- trouble breathing or swallowing
- swelling of the face, lips, or tongue
- skin rash or flushing of your skin
- feeling dizzy or faint
- fever
- fast heartbeat

- **Heart and blood vessel (cardiovascular) problems:** SCEMBLIX may cause heart and blood vessel problems, including heart attack, stroke, blood clots or blockage of your arteries, heart failure, and abnormal heartbeat, which can be serious and may sometimes lead to death. In the majority of cases, these heart and blood vessel problems happened in people with risk factors or a history of these problems, and previously treated with other tyrosine kinase inhibitor (TKI) medicines. Your doctor may monitor you for heart and blood vessel problems and treat you as needed during treatment with SCEMBLIX. Tell your doctor or get medical help right away if you get:

- shortness of breath
- chest pain or pressure
- a feeling like your heart is beating too fast or you feel abnormal heartbeats
- swelling in your ankles or feet
- dizziness
- weight gain
- numbness or weakness on one side of your body
- decreased vision or loss of vision
- trouble talking
- pain in your arms, legs, back, neck, or jaw
- headache
- severe stomach-area (abdominal) pain

The most common side effects of SCEMBLIX include:

- muscle, bone, or joint pain
- rash
- tiredness
- nose, throat, or sinus (upper respiratory tract) infections
- headache
- stomach-area (abdominal) pain
- diarrhea
- decreased white blood cell counts, platelet counts, and red blood cell counts

The most common side effects of SCEMBLIX include: (continued)

- decreased blood calcium corrected levels
- increased blood pancreas enzyme (lipase and amylase) levels
- increased blood fat (cholesterol and triglycerides) levels
- increased blood uric acid levels
- increased blood liver enzyme levels
- increased blood alkaline phosphatase levels
- increased blood creatine kinase levels

Your doctor may change your dose, temporarily stop, or permanently stop treatment with SCEMBLIX if you have certain side effects.

SCEMBLIX may cause fertility problems in females. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

These are not all the possible side effects of SCEMBLIX. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

How should I store SCEMBLIX?

- Store SCEMBLIX at room temperature between 68°F to 77°F (20°C to 25°C)
- Store SCEMBLIX in the original container to protect it from moisture

Keep SCEMBLIX and all medicines out of the reach of children.

General information about the safe and effective use of SCEMBLIX

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SCEMBLIX for a condition for which it was not prescribed. Do not give SCEMBLIX to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for more information about SCEMBLIX that is written for health care professionals.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

FOR ADULTS WITH NEWLY DIAGNOSED OR PREVIOUSLY TREATED Ph+ CML-CP



VISIT SCEMBLIX.COM



In a head-to-head clinical study of adults with newly diagnosed Ph+ CML-CP

**More people achieved MMR with SCEMBLIX than with commonly used TKIs* at 48 weeks**

- SCEMBLIX vs commonly used TKIs*: 68% (136 of 201 patients) vs 49% (100 of 204 patients)
- SCEMBLIX vs GLEEVEC*: 69% (70 of 101 patients) vs 40% (41 of 102 patients)

**More people were able to stay on SCEMBLIX for 48 weeks***

- SCEMBLIX vs commonly used TKIs*: 4.5% (9 of 200 patients) vs 10.4% (21 of 201 patients) had to stop treatment due to side effects
- By 48 weeks, 90% of patients on SCEMBLIX were still on treatment vs 81% of patients on the most commonly used TKIs*

In this clinical study, the most common side effects reported ($\geq 20\%$) with SCEMBLIX were pain in the muscles, bones, or joints.

Ask your doctor about SCEMBLIX.

*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

APPROVED USES

SCEMBLIX is a prescription medicine used to treat adults with:

- Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
 - The approval of SCEMBLIX in patients newly diagnosed is based on a study that measured major molecular response (MMR) rate. There are ongoing studies to confirm the clinical benefit of SCEMBLIX for this use and how SCEMBLIX works over a longer period of time
- Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15.



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SCEMBLIX®
(asciminib) 20 mg, 40 mg tablets