

ORAL CHEMOTHERAPY EDUCATION



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ASCIMINIB

Name of your medication

Generic name — asciminib (as-KIM-uh-nib)

Brand name — SCEMBLIX®

Common uses

Asciminib is used to treat chronic myeloid leukemia (CML).

Asciminib may also be used for other treatments.

Dose and schedule

Taking asciminib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of asciminib is:
 - 80 milligrams (80 mg) to be taken by mouth at a scheduled time once a dayOR
 - 40 milligrams (40 mg) to be taken by mouth at a scheduled time twice a day approximately 12 hours apartOR
 - 200 milligrams (200 mg) to be taken by mouth at a scheduled time twice a day approximately 12 hours apart**

** Side effects of asciminib vary with higher dose (200 mg twice a day).
- Asciminib should be taken without food, at the same time each day. Do not eat for at least 2 hours before and 1 hour after taking asciminib.
- Asciminib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow asciminib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of asciminib:
 - For once daily dosing: only take the missed dose if it has been less than 12 hours since you were supposed to take it. Then take the next dose at the regularly scheduled time.
 - For twice daily dosing: only take the missed dose if it has been less than 6 hours since you were supposed to take it. Then take the next dose at the regularly scheduled time.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose and let your care provider know about any missed doses.

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ASCIMINIB

Drug and food interactions

- ❑ Asciminib has many drug interactions; please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- ❑ Grapefruit or grapefruit juice may interact with asciminib; avoid eating or drinking these during treatment with asciminib.
- ❑ Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle asciminib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- ❑ Store asciminib at room temperature (68 to 77 F) in a dry location away from light.
- ❑ Keep asciminib out of reach of children and pets.
- ❑ Leave asciminib in the provided packaging until it is ready to be taken.
- ❑ Whenever possible, you should give asciminib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the asciminib to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the asciminib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- ❑ A daily pill box or pill reminder is **NOT** recommended to be used with asciminib.
- ❑ If you have any unused asciminib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of asciminib.
- ❑ If you are traveling, put your asciminib in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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ASCIMINIB

Side Effects of Asciminib**

Below are common side effects that have been known to happen in about one-third or more of patients taking asciminib; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

** Side effects of asciminib vary with higher dose (200 mg twice a day).

Possible Side Effect	Management
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently and do not pick your nose. • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. • When shaving use an electronic razor instead of razor blades. • Use a nail file instead of a nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, blood in your urine or stool, coughing up blood, or prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or "hold" your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>
<p>Decreased white blood cells (WBCs) and increased risk for infections</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

Continued on the next page

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Possible Side Effect	Management
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7 to 8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between “work” and “rest.” • Stay as active as possible, but know that it is okay to rest as needed, too. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Muscle or joint pain</p>	<ul style="list-style-type: none"> • Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. • Stay as active as possible, but know that it is OK to rest as needed, too. • Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.</p>
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Stay as active as possible, but know that it is okay to rest as needed, too. • Avoid operating heavy machinery if you feel too tired.
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High creatine kinase • Increased cholesterol 	<p>Changes in some lab values may occur and will be monitored by a simple blood test. More severe changes may occur, which can be a sign of a serious problem.</p> <ul style="list-style-type: none"> • Unexplained muscle aches or pains

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ASCIMINIB

Serious side effects

- Bone marrow suppression is a decrease in the number of white blood cells, red blood cells, and platelets that can be severe with asciminib. Speak to your care provider to know when you need to have laboratory tests done to monitor your blood cell counts. You also may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.
- Asciminib may be harmful to your pancreas. Seek medical attention if you have severe stomach pain or tenderness, fever, or vomiting.
- You may have high blood pressure while taking asciminib. Take your blood pressure on a regular basis and let your care team know of any large increases in blood pressure.
- Severe allergic reactions are a rare but serious side effect of asciminib. Immediately seek medical attention if you notice difficulty breathing, swelling of the mouth or tongue, or a serious rash.
- Asciminib can cause cardiovascular toxicity which is a condition when there is damage to your heart muscle and/or blood vessels. Seek medical attention right away if you have any chest pain or tightness.
- Asciminib may cause a condition called QT or QTc prolongation which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life-threatening. Tell your care team right away if you feel faint, lightheaded, dizzy, or if you feel your heart beating irregularly or fast, while taking asciminib.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since asciminib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take asciminib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems:
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or asciminib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

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ASCIMINIB

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking asciminib. Males and females of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 week after the last dose of asciminib.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking asciminib and for 1 week after the last dose of asciminib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.

Obtaining medication

- Talk with your care provider about the process for obtaining your asciminib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.us.scemblix.com>

Product prescribing information: <https://www.novartis.us/sites/www.novartis.us/files/scemblix.pdf>

Product resources: <https://www.novartis.com/patients-and-caregivers>

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Additional instructions

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Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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