



CRESEMBA[®]
(isavuconazonium sulfate)
74.5 mg • 186 mg capsules

PATIENT EDUCATION

This brochure includes helpful information about CRESEMBA[®] (isavuconazonium sulfate) capsules. Be sure to talk to your/or your child's healthcare provider or pharmacist if you have any questions.

Please see Important Safety Information throughout brochure. [Click here](#) for Patient Information and Full Prescribing Information for CRESEMBA.

WHAT IS AN INVASIVE FUNGAL INFECTION?

Fungi, like bacteria, live all around us. They can be in the air, soil, plants, and water. Most fungi do not make humans sick, but some can get into the body or blood and cause a serious, at times life-threatening, infection. This is called an invasive fungal infection.

WHAT ARE INVASIVE ASPERGILLOSIS AND INVASIVE MUCORMYCOSIS?

Many types of fungi can cause invasive fungal infections. Two such invasive fungal infections are:

Aspergillosis (as-per-juh-LOH-sis)

is a fungal infection caused by a mold called *Aspergillus*.

Mucormycosis (mew-cor-my-COH-sis)

also called zygomycosis (zy-go-my-COH-sis), is a fungal infection caused by a group of molds called Mucormycetes.

WHO IS AT RISK FOR INVASIVE ASPERGILLOSIS AND INVASIVE MUCORMYCOSIS?

Anyone can be at risk for getting an invasive fungal infection. Some conditions may increase your risk. People who have certain kinds of cancer or who have had an organ or stem cell transplant are more at risk of getting an invasive fungal infection. If you have diabetes, HIV/AIDS, or severe burns, you can also be at risk.

Getting a fungal infection when you already have another illness can make it harder to fight your illness. It can be even more difficult if your immune system is weak. With the right treatment plan, it is possible to treat invasive aspergillosis and invasive mucormycosis.

HOW ARE INVASIVE ASPERGILLOSIS AND INVASIVE MUCORMYCOSIS TREATED?

Fungal infections are treated differently based on the type of fungus that causes the infection. Invasive aspergillosis and invasive mucormycosis are often treated with antifungal medicine. This medicine can help get rid of or slow the spread of the fungus.

In the hospital, you may be given the medicine through an intravenous (IV) line into a vein or through a feeding tube. Many antifungal medicines are also available in pills. You may have to start treatment with IV medicine and then switch to a pill.

ABOUT CRESEMBA

186 mg CRESEMBA capsules have a reddish-brown body and white cap. They come in a box that contains two blister sheets. There is a total of 14 capsules per box.

74.5 mg CRESEMBA capsules have a reddish-brown body and cap. They come in a box that contains seven blister sheets. There is a total of 35 capsules per box.



Capsules not actual size.

Please see additional Important Safety Information throughout brochure. [Click here](#) for Patient Information and Full Prescribing Information for CRESEMBA.

WHAT IS CRESEMBA?

CRESEMBA is a prescription medicine used to treat certain types of fungal infections in the blood or body called invasive aspergillosis and invasive mucormycosis as follows:

- **CRESEMBA for injection:** adults and children 1 year of age and older
- **CRESEMBA capsules:** adults and children 6 years of age and older who weigh 35 pounds (16 kg) or more

It is not known if CRESEMBA capsules are safe and effective in children younger than 6 years of age or who are 6 years of age and older but weigh less than 35 pounds (16 kg).

It is not known if CRESEMBA is safe and effective in children under 1 year of age.

IMPORTANT SAFETY INFORMATION

Who should not take CRESEMBA?

Do not take CRESEMBA if you or your child:

- are allergic to CRESEMBA or any of the ingredients. See the end of the [Patient Information](#) for a complete list of ingredients in CRESEMBA.
- are taking any of the following medicines:
 - ketoconazole
 - carbamazepine
 - long-acting barbiturates
 - high-dose ritonavir
 - St. John's wort (herbal supplement)
 - rifampin
- have a genetic problem that affects the electrical system of the heart (familial short QT syndrome)

Talk to your or your child's healthcare provider or pharmacist if you are not sure if you are taking any of these medicines or have any of the conditions listed above.

Do not start taking new medicines without talking to your or your child's healthcare provider or pharmacist.

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WHAT IS THE RECOMMENDED DOSING OF CRESEMBA IN ADULTS?

Take CRESEMBA® (isavuconazonium sulfate) exactly as your or your child's healthcare provider tells you to take it.

If you or your child are just starting on CRESEMBA, you may need to take it more frequently at first. This is called a loading dose.

Once you or your child complete the loading dose, you should continue to take CRESEMBA once a day for as long as your healthcare provider tells you. This is called a maintenance dose.

Recommended dosing of CRESEMBA in adults			
Loading dose (Day 1 and Day 2)		Maintenance dose* (Day 3 and on)	
Take two 186 mg capsules at the same time, every 8 hours		Take two 186 mg capsules at the same time, once a day	
			
OR			
Take five 74.5 mg capsules at the same time, every 8 hours		Take five 74.5 mg capsules at the same time, once a day	
			

Capsules not actual size.

*Start maintenance dose 12 to 24 hours after the last loading dose.

You or your child can take CRESEMBA with or without food.

Be sure to swallow CRESEMBA capsules whole. Do not chew, crush, dissolve, or open the capsules.

Please see additional Important Safety Information throughout brochure. [Click here](#) for Patient Information and Full Prescribing Information for CRESEMBA.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Before you or your child take CRESEMBA, tell your healthcare provider about all of your medical conditions, including if you or your child:

- have or ever had an abnormal heart rate or rhythm. Your healthcare provider may order a test to check your heart (ECG) before starting CRESEMBA.
- have liver problems. Your healthcare provider may do blood tests to make sure you can take CRESEMBA.
- have ever had an allergic reaction to other antifungal medicines such as ketoconazole, fluconazole, itraconazole, voriconazole or posaconazole.
- are pregnant or plan to become pregnant. CRESEMBA may harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant. Women who can become pregnant should use effective birth control while taking CRESEMBA and for 28 days after the last CRESEMBA dose. Talk to your healthcare provider about birth control methods that may be right for you.
- are breastfeeding or plan to breastfeed. CRESEMBA can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take CRESEMBA. You should not breastfeed while taking CRESEMBA.

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WHAT IS THE RECOMMENDED DOSING OF CRESEMBA IN CHILDREN (AGED 6 TO UNDER 18 YEARS OLD)?

Recommended dosing of CRESEMBA in children (aged 6 to under 18 years old) ³			
Body Weight (kg)	Loading Dose (Day 1 and Day 2)		Maintenance Dose* (Day 3 and on)
For those weighing 16 kg to <18 kg	Take two 74.5 mg capsules at the same time, every 8 hours		Take two 74.5 mg capsules at the same time, once a day
			
For those weighing 18 kg to <25 kg	Take three 74.5 mg capsules at the same time, every 8 hours		Take three 74.5 mg capsules at the same time, once a day
			
For those weighing 25 kg to <32 kg	Take four 74.5 mg capsules at the same time, every 8 hours		Take four 74.5 mg capsules at the same time, once a day
			
For those weighing ≥32 kg	Take five 74.5 mg capsules at the same time, every 8 hours		Take five 74.5 mg capsules at the same time, once a day
			

Capsules not actual size.

*Start maintenance dose 12 to 24 hours after the last loading dose.

You or your child can take CRESEMBA with or without food.

Be sure to swallow CRESEMBA capsules whole. Do not chew, crush, dissolve, or open the capsules.

Please see additional Important Safety Information throughout brochure. [Click here](#) for Patient Information and Full Prescribing Information for CRESEMBA.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. CRESEMBA may affect the way other medicines work, and other medicines may affect how CRESEMBA works and can cause side effects.

How should I or my child take CRESEMBA?

- Take CRESEMBA exactly as your or your child's healthcare provider tells you to take it.
- **Do not** stop taking CRESEMBA until your or your child's healthcare provider tells you to.
- If you or your child take too much CRESEMBA, call your healthcare provider or go to the nearest hospital emergency room right away.
- CRESEMBA capsules can be taken with or without food.
- Swallow CRESEMBA capsules whole. **Do not** chew, crush, dissolve, or open the capsules.
- CRESEMBA for injection can be given through a nasogastric tube by your or your child's healthcare provider.
- **Do not** give CRESEMBA capsules through a nasogastric tube.

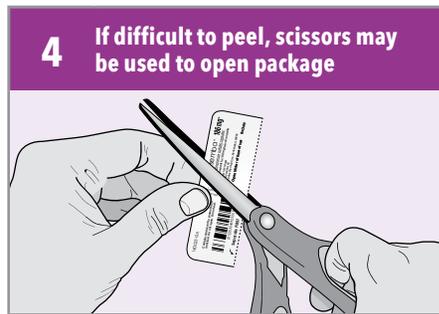
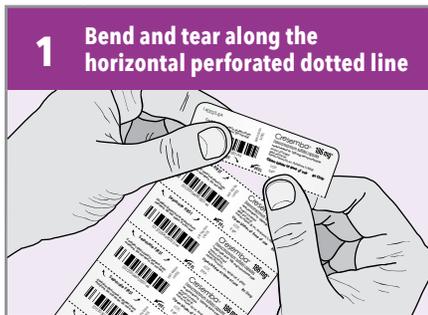
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HOW DO I OPEN CRESEMBA CAPSULES BLISTER PACKAGING?

CRESEMBA® (isavuconazonium sulfate) capsules are in child-resistant blister packaging. Each blister section contains two pockets—one pocket for the CRESEMBA capsule and one pocket for the desiccant. The desiccant is a substance that protects the capsule from moisture and keeps it dry.

- **Only** open the blister packaging at time of use. Make sure only the CRESEMBA capsule pocket is opened.
- **Do not** puncture the pocket containing the desiccant.
- **Do not** swallow or use the desiccant.

To open the blister packaging, open from the printed side as shown below.



Please see additional Important Safety Information throughout brochure. [Click here](#) for Patient Information and Full Prescribing Information for CRESEMBA.

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are the possible side effects of CRESEMBA?

CRESEMBA may cause serious side effects, including:

- **liver problems.** Liver problems can happen in some people taking CRESEMBA. Some people who also have other serious medical problems may get severe liver problems which can lead to hepatitis, gallbladder problems, liver failure or death. Your or your child's healthcare provider should do blood tests to check your liver before you start and while you are taking CRESEMBA. Call your or your child's healthcare provider right away if you have any of the following symptoms of liver problems:
 - itchy skin
 - yellowing of your eyes
 - feeling very tired
 - nausea or vomiting
 - flu-like symptoms
- **infusion reactions.** Infusion reactions can happen in people receiving CRESEMBA intravenously. If an infusion reaction happens, your or your child's infusion will be stopped. Symptoms of an infusion reaction may include:
 - low blood pressure
 - dizziness
 - changes in your sense of touch (hypoesthesia)
 - difficulty breathing
 - numbness and tingling
 - chills

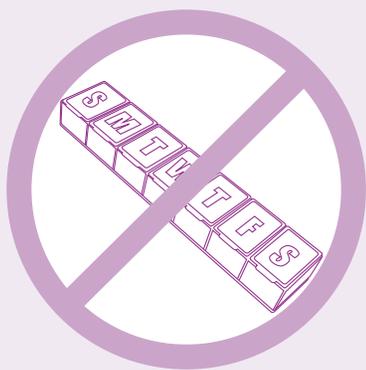
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HOW SHOULD I STORE CRESEMBA CAPSULES?

- Store CRESEMBA® (isavuconazonium sulfate) capsules at room temperature 68°F to 77°F (20°C to 25°C).
- Keep CRESEMBA capsules in the original package and protect it from moisture.
- **Do not** remove CRESEMBA from original packaging until your scheduled dose.
- Safely throw away medicine that is out of date or no longer needed.
- **Keep CRESEMBA and all medicines out of the reach of children.**

Do not store CRESEMBA capsules in a standard pill box.

CRESEMBA is sensitive to moisture and should not be removed from original packaging until the time of your scheduled dose.



Please see additional Important Safety Information throughout brochure. [Click here](#) for Patient Information and Full Prescribing Information for CRESEMBA.

IMPORTANT SAFETY INFORMATION (CONTINUED)

CRESEMBA may cause serious side effects, including:

- **severe allergic reactions.** Severe allergic reactions including death can happen in some people taking CRESEMBA. Symptoms of a severe allergic reaction may include:
 - swelling of your face, lips, mouth, or tongue
 - wheezing
 - skin rash redness, or swelling
 - fast heartbeat or pounding in your chest
 - trouble breathing
 - severe itching
 - dizziness or fainting
 - sweating

Stop taking CRESEMBA and call your or your child's healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.

- **drug interactions with cyclosporine, sirolimus, or tacrolimus.** If you or your child take CRESEMBA with cyclosporine, sirolimus, or tacrolimus, your blood levels of cyclosporine, sirolimus, or tacrolimus may increase. Serious side effects can happen in your or your child's kidney or brain if you have high levels of cyclosporine, sirolimus, or tacrolimus in your blood. Your or your child's healthcare provider should do blood tests to check your levels of cyclosporine, sirolimus, or tacrolimus if you are taking these medicines while taking CRESEMBA. Tell your or your child's healthcare provider right away if you have swelling in your arm or leg or shortness of breath.
- **medicine interactions.** Taking CRESEMBA with some other medicines may affect the way other medicines work causing serious side effects. Other medicines may affect the way CRESEMBA works, causing serious side effects. Tell your or your child's healthcare provider about all the medicines you take.

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SAVINGS AND SUPPORT FOR ELIGIBLE COMMERCIALY INSURED PATIENTS ON CRESEMBA® (isavuconazonium sulfate)



Download and print a CRESEMBA Savings Card at activatethecard.com/CRESEMBA.

Eligible commercially insured patients can start saving on their CRESEMBA prescription today!*

*By enrolling in the CRESEMBA Patient Savings Program ("Program"), the patient or the patient's legal representative (e.g., parent or legal guardian) acting on behalf of the patient, attests that the patient currently meets the eligibility criteria and will comply with the following terms and conditions: **The Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD) Veterans Affairs (VA), TRICARE, or any state pharmaceutical assistance program.** Offer is not valid for cash paying patients. Offer is not health insurance and is void where prohibited by law. Certain rules and restrictions, including a copay assistance limit of \$4,000 per calendar year, apply. Astellas reserves the right to revoke, rescind, or amend this offer without notice. For full terms and conditions, visit ActivateTheCard.com/CRESEMBA.

CRESEMBA Support Solutions is also available to help you understand your insurance coverage and to provide assistance to patients who may have trouble accessing their medication.

Please call us or scan to visit our website for more information.



1-800-477-6472
Mon-Fri, 9 AM to 8 PM ET



CRESEMBA Support Solutions.com

IMPORTANT SAFETY INFORMATION (CONTINUED)

The most common side effects of CRESEMBA in adults include:

- nausea
- vomiting
- diarrhea
- headache
- changes in the level of a liver enzyme in your blood
- low potassium
- constipation
- shortness of breath
- cough
- swelling of arms or legs
- back pain

The most common side effects of CRESEMBA in children include:

- diarrhea
- stomach pain
- vomiting
- changes in the level of a liver enzyme in your blood
- rash
- nausea
- itching
- headache

Tell your or your child's healthcare provider if you have any side effect that bothers you or that does not go away.

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](tel:1-800-FDA-1088).

For further information, please talk to your healthcare provider and [click here](#) for Patient Information and Full Prescribing Information for CRESEMBA.

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