Patient Information
CRESEMBA® (Crē sem' bah)
(isavuconazonium sulfate)
capsules, for oral administration

CRESEMBA® (Crē sem' bah)
(isavuconazonium sulfate)
for injection, for intravenous administration

Read this Patient Information before you start taking CRESEMBA and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is CRESEMBA?

CRESEMBA is a prescription medicine used to treat people 18 years of age and older with certain types of fungal infections in the blood or body called "aspergillosis," and "mucormycosis" (zygomycosis).

It is not known if CRESEMBA is safe and effective in children under 18 years of age.

Who should not take CRESEMBA?

Do not take CRESEMBA if you:

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

Talk to your 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 healthcare provider or pharmacist.

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

- 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 medications 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.

Tell your healthcare provider about all the medicines you 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.

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I take CRESEMBA capsules?

- Take CRESEMBA exactly as your healthcare provider tells you to take it.
- **Do not** stop taking CRESEMBA until your healthcare provider tells you to.
- If you take too much CRESEMBA, call your healthcare provider.
- CRESEMBA capsules can be taken with or without food.

- Swallow CRESEMBA capsules whole.
- **Do not** chew, crush, dissolve, or open the capsules.

Instructions on opening CRESEMBA capsules blister packaging:

CRESEMBA 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 to protect the capsule from moisture (located to the left of the capsule).

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

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 healthcare provider should do blood tests to check your liver before you start and while you are taking CRESEMBA. Call your healthcare provider right away if you have any of the following symptoms of liver problems:
  - o itchy skin
  - o yellowing of your eyes
  - o flu-like symptoms
  - o nausea or vomiting
  - o feeling very tired
- **infusion reactions.** Infusion reactions can happen in people receiving CRESEMBA intravenously. If an infusion reaction happens, your infusion will be stopped. Symptoms of an infusion reaction may include:
  - o low blood pressure
  - o chills
  - o numbness and tingling
  - o difficulty breathing
  - o dizziness
  - o changes in your sense of touch (hypoesthesia)
- **severe allergic and skin reactions.**
- **drug interactions with cyclosporine, sirolimus, or tacrolimus.** If you take CRESEMBA with cyclosporine, sirolimus, or tacrolimus, your blood levels of cyclosporine, sirolimus, or tacrolimus may increase. Serious side effects can happen in your kidney or brain if you have high levels of cyclosporine, sirolimus, or tacrolimus in your blood. Your 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 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 healthcare provider about all the medicines you take.

The most common side effects of CRESEMBA 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

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

These are not all the possible side effects of CRESEMBA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store CRESEMBA capsules?

- Store CRESEMBA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep CRESEMBA in the original package and protect it from moisture.
- **Do not** remove CRESEMBA from original packaging.
- **Do not** put CRESEMBA in pill boxes or pill organizers.
- Safely throw away medicine that is out of date or no longer needed.
- **Keep CRESEMBA and all medicines out of the reach of children.**

General information about the safe and effective use of CRESEMBA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use CRESEMBA for a condition for which it was not prescribed. Do not give CRESEMBA to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about CRESEMBA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about CRESEMBA that is written for healthcare professionals.

What are the ingredients of CRESEMBA?

Active ingredient: isavuconazonium sulfate.

Inactive ingredients: magnesium citrate, microcrystalline cellulose, talc, colloidal silicon dioxide, stearic acid, hypromellose, red iron oxide, titanium dioxide, purified water, gellan gum, potassium acetate, disodium edetate, sodium laurylsulfate, shellac, propylene glycol, strong ammonia solution, potassium hydroxide, black iron oxide.

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For more information go to www.CRESEMBA.com or call 1-800-727-7003.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 12/2019