

# CRESEMBA™ CAPSULES

Isavuconazonium sulfate (Equivalent to Isavuconazole 100 mg)

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## What Cresemba is used for

Cresemba is used in adults (18 years of age and older) to treat the following fungal infections:

- invasive aspergillosis;
- mucormycosis in patients for whom a treatment with amphotericin B is not appropriate.

## How Cresemba works

Cresemba is an anti-fungal medicine that contains the active substance isavuconazole. Isavuconazole works by killing or stopping the growth of the fungus, which causes the infection.

## Before you use Cresemba

### - When you must not use it

Do not take Cresemba:

- if you are allergic to isavuconazole or any of the other ingredients present in this medicine
- if you have a heart beat problem called 'familial short QT syndrome'
- if you are using any of the following medicines:
  - ketoconazole, used for fungal infections,
  - high doses of ritonavir (more than 200 mg every 12 hours), used for HIV,
  - rifampicin and rifabutin, used for tuberculosis,
  - carbamazepine and phenytoin, used for epilepsy,
  - barbiturate medicines like phenobarbital, used for epilepsy and sleep disorders,
  - St. John's wort, a herbal medicine used for depression,
- efavirenz and etravirine, used for HIV,
- nafcillin, used for bacterial infections.

## Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Do not take Cresemba if you are pregnant, unless your doctor tells you otherwise. This is because it is not known if it may affect or harm your unborn baby. Your doctor may prescribe you this medicine only if you have a severe or potentially life-threatening fungal infection and benefits to you outweigh the possible risks to the foetus.

Do not breast-feed if you are taking Cresemba as it can pass into your breast milk and may harm your baby. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start to use it

Talk to your doctor, pharmacist or nurse before taking Cresemba:

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- if you are taking other medicinal products known to decrease the QT interval, such as rufinamide,
- if you are suffering from severe liver disease or have high levels of liver enzymes as treatment with Cresemba may result in hepatitis.

## - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- ketoconazole, used for fungal infections,
- high doses of ritonavir (more than 200 mg every 12 hours), used for HIV,
- rifampicin and rifabutin, used for tuberculosis,
- carbamazepine and phenytoin, used for epilepsy,
- barbiturate medicines like phenobarbital, used for epilepsy and sleep disorders,
- St. John's wort, a herbal medicine used for depression,
- efavirenz and etravirine, used for HIV,
- nafcillin, used for bacterial infections,
- rufinamide or other medicines which decrease the QT interval on the heart tracing (ECG),
- aprepitant, used to prevent nausea and vomiting by cancer treatment,
- prednisone, used for rheumatoid arthritis,
- metformin and pioglitazone, used for diabetes,
- ciclosporin, tacrolimus, sirolimus and mycophenolate mofetil (MMF), 'immunosuppressants' used after having a transplant,

- cyclophosphamide, vincristine and vinblastine, used for cancer,
- digoxin, used to treat heart failure or an uneven heartbeat,
- colchicine, used for gout attack,
- dabigatran etexilate, used to stop blood clots after hip or knee replacement surgery,
- clarithromycin, used for bacterial infections,
- saquinavir, fosamprenavir, indinavir, nevirapine, lopinavir/ritonavir combination, used for HIV,
- alfentanil, fentanyl, used against severe pain,
- midazolam, used for anxiety, agitation and sedation,
- bupropion, used for depression,
- daunorubicin, doxorubicin, imatinib, irinotecan, lapatinib, mitoxantrone, topotecan, used for different sorts of cancer.

## How to use Cresemba

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Starting dose for the first two days (48 hours) is two capsules three times a day (every 8 hours). Usual dose after the first two days is two capsules once a day (12 to 24 hours after the last loading dose).

Cresemba is also available as powder for concentrate for solution for infusion containing 200 mg isavuconazole.

Loading dose is not required when switching between formulations.

You will take this dose until your doctor tells you otherwise.

Cresemba can be taken with or without food. Swallow the capsules whole. Do

not chew, crush, dissolve or open the capsules.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue taking Cresemba for as long as your doctor recommends.

The duration of treatment with Cresemba may be longer than 6 months if your doctor considers this necessary.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many capsules may cause side effects such as:

- headache, feeling dizzy, restless or sleepy
- tingling, reduced sense of touch or sensation in the mouth
- disturbance in attention, hot flushes, anxiety, joint pain
- changes in the way things taste, dry mouth, diarrhoea, vomiting
- feeling your heart beat, faster heart rate, being more sensitive to light

## While you are using it

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## - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Cresemba.

Tell your doctor immediately if you become pregnant while taking this medication.

## - Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Cresemba to anyone else, even if they have the same symptoms or condition as you.

## - Things to be careful of

### *Driving and using machines*

This medicine may affect your ability to drive or use machines. If the capsules make you confused, dizzy, tired, or cause partial or complete loss of consciousness, do not drive or use machines and contact your doctor immediately.

## **Side effects**

Like all medicines, Cresemba can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Stop taking Cresemba and tell your doctor straight away if you develop any severe skin reactions.

If you have any liver disease, your doctor may monitor you for any side effects during the treatment.

## Common side effects: may affect greater than or equal to 1 in 10 people

- low potassium in your blood
- decreased appetite
- delirium
- headache
- sleepiness
- inflammation of a vein that could lead to a blood clot
- shortness of breath, sudden and severe difficulty of breathing
- vomiting
- diarrhea
- nausea
- stomach pain
- changes in blood tests of liver function
- rash
- itching
- kidney failure
- chest pain
- tiredness

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [nprra.moh.gov.my](http://nprra.moh.gov.my) [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## **Storage and Disposal of Cresemba**

### - Storage

Keep out of the reach and sight of children.

Store below 30°C. Store in the original packaging in order to protect from moisture.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **Product Description**

### - What it looks like

Hard capsule

Swedish Orange (reddish-brown) capsule body marked with "100" in black ink and a white cap marked with "C" in black ink. Capsules length: 24.2 mm.

## - Ingredients

- Active ingredient  
Isavuconazole

- Inactive ingredients

### Capsule contents

magnesium citrate (anhydrous)  
microcrystalline cellulose  
talc  
silica, colloidal anhydrous  
stearic acid

### Capsule shell

hypromellose  
red iron oxide (E172) (capsule body only)  
titanium dioxide (E171)  
gellan gum  
potassium acetate  
disodium edetate  
sodium lauryl sulfate

### Printing ink

shellac  
propylene glycol  
potassium hydroxide  
black iron oxide (E172)

## - MAL number:

MAL21076003ACRZ

## **Manufacturer**

SwissCo Services AG  
Bahnhofstrasse 14, Sisseln, 4334  
Switzerland

## **Product Registration Holder**

Pfizer (Malaysia) Sdn. Bhd.  
Level 10 & 11,  
Wisma Averis, Tower 2,  
Avenue 5, Bangsar South,  
No. 8 Jalan Kerinchi,  
59200 Kuala Lumpur, Malaysia

## **Date of Revision**

07/08/2024

## **Serial Number**

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