

Cresemba®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using CRESEMBA?

CRESEMBA contains the active ingredient isavuconazole. CRESEMBA is used to treat fungal infections such as invasive aspergillosis and invasive mucormycosis. This medicine works by preventing the growth of the fungal organisms causing your infection. For more information, see Section [1. Why am I using CRESEMBA?](#) in the full CMI.

2. What should I know before I use CRESEMBA?

Do not use if you have ever had an allergic reaction to isavuconazole or any of the ingredients listed at the end of the CMI, or any other similar medicines such as

ketoconazole, fluconazole, itraconazole, voriconazole or posaconazole.

Do not use CRESEMBA if you are taking any of the medicine listed in section [3. What if I am taking other medicines?](#)

Do not take this medicine if you have familial short QT syndrome (Disorder of the heart).

CRESEMBA should not be taken during pregnancy or breastfeeding, unless indicated by your doctor. Effective contraception should be used in woman of childbearing potential.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use CRESEMBA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CRESEMBA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use CRESEMBA?

CRESEMBA is available as capsules for oral use or as an IV powder for injection. CRESEMBA capsules should be swallowed whole with a full glass of water. Do not chew, crush, dissolve or open the capsules. CRESEMBA IV Injection is given as a slow injection into

a vein (intravenous infusion). It must only be given by a doctor or trained nurse and is prepared prior to injection. More instructions can be found in Section [4. How do I use CRESEMBA?](#) in the full CMI.

5. What should I know while using CRESEMBA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using CRESEMBA.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• This medicine may cause confusion, tiredness and sleepiness in some people. If you have any of these symptoms, do not drive,

	operate machinery or do anything else that could be dangerous.
Looking after your medicine	<ul style="list-style-type: none"> ● <u>Capsules</u>: Keep your capsules in the original pack until it is time to take them and store in a cool dry place where the temperature stays below 25°C. ● <u>IV Powder for injection</u>: CRESEMBA IV Injection will be stored in the pharmacy or on the hospital ward. It is kept in a refrigerator where the temperature stays between 2-8°C.

For more information, see Section [5. What should I know while using CRESEMBA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include nausea, vomiting, shortness of breath, abdominal pain and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Cresemba[®]

Active ingredient(s): *Isavuconazole* (isa-vu-con-a-zole)

Consumer Medicine Information (CMI)

This leaflet answers some common questions about CRESEMBA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CRESEMBA against the benefits they expect it will have for you.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CRESEMBA.

Where to find information in this leaflet:

[1. Why am I using CRESEMBA?](#)

[2. What should I know before I use CRESEMBA?](#)

[3. What if I am taking other medicines?](#)

[4. How do I use CRESEMBA?](#)

[5. What should I know while using CRESEMBA?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I using CRESEMBA?

CRESEMBA contains the active ingredient isavuconazole.

This medicine belongs to a group of medicines called triazole antifungals.

This medicine is used to treat fungal infections such as:

- Invasive aspergillosis (as-pur-ji-losis), an infection caused by a fungus called *Aspergillus* (as-pur-jilus).
- Mucormycosis (mu-cor-mi-cosis), an infection caused by a fungus called *Mucorales* (mu-cor-alus) where treatment with amphotericin (am-fo-teri-cin) B is not appropriate.

This medicine works by preventing the growth of the fungal organisms causing your infection.

2. What should I know before I use CRESEMBA?

Warnings

Do not use CRESEMBA if:

1. you are allergic to isavuconazole, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin
2. You are allergic to any other similar medicines such as ketoconazole, fluconazole, itraconazole, voriconazole or posaconazole.
 3. You are taking any of the medicine listed in section 3 below: What if I am taking other medicines?

Do not take this medicine if you have familial short QT syndrome (Disorder of the heart). It may cause your heart to beat irregularly.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Check with your doctor if you:

- have any other medical conditions including:
 - allergies to any other medicines, foods, preservatives or dyes or any other medicines, especially antifungal medicines such as itraconazole), fluconazole, posaconazole or ketoconazole.
 - heart problems
 - any problems affecting your liver
 - any problems affecting your kidneys
- take any medicines for any other condition
- Your doctor should do blood tests to check your liver before you start and while you are having treatment with CRESEMBA.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

CRESEMBA should not be taken during pregnancy, unless indicated by your doctor. Effective contraception should be used in woman of childbearing potential. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

CRESEMBA should not be taken whilst breastfeeding, unless indicated by your doctor.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

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

Some medicine and CRESEMBA should not be taken together. These include:

- ketoconazole, a medicine used to treat fungal infections.
- ritonavir, a medicine used to treat HIV infection where the dose is greater than 200 mg or more twice a day.
- rifabutin, an antibiotic used to treat tuberculosis.
- rifampicin, a medicine used to treat tuberculosis and other infections.
- carbamazepine, a medicine used to treat epilepsy.
- Long-acting barbiturates such as phenobarbital, medicines used to treat severe insomnia and seizures.
- phenytoin, a medicine used to treat epilepsy.
- efavirenz and etravine, medicines used to treat HIV infection.

- St. John's Wort, a herbal medicine used to treat depression.
- nafcillin, a medicine used to bacterial infections.

Some medicines may interfere with CRESEMBA and affect how it works.

These include:

- rufinamide, a medicine used to treat seizures.
- aprepitant, a medicine used to treat nausea and vomiting.
- prednisone, a steroidal medicine use to treat a variety of conditions.
- pioglitazone, a medicine use in the treatment of diabetes.
- ciclosporin, sirolimus and tacrolimus, medicines used to prevent organ transplant rejection or to treat certain problems with the immune system.
- digoxin, medicine used to various heart conditions.
- colchicine, a medicine used in the treatment of gout.
- dabigatran etexilate, a medicine used in the treatment of blood clots (Deep Vein Thrombosis and Pulmonary Embolism).
- clarithromycin used to treat bacterial infections.
- saquinavir, indinavir, nevirapine, fosamprenavir, lopinavir/ritonavir combination used to treat HIV infection.
- alfentanil, fentanyl, used to treat strong pain.
- vincristine, vinblastine, used to treat cancer.
- mycophenolate mofetil, used in transplant patients.
- midazolam, used to treat severe insomnia.

- Bupropion, used for smoking cessation and to treat depression.
- metformin, a medicine used in the treatment of diabetes
- daunorubicin, cyclophosphamide, doxorubicin, irinotecan, topotecan and mitoxantrone, medicines used in treating cancer.
- imatinib and lapatinib medicine used in the treatment of cancer.
- lovastatin, a medicine used in the treatment of high cholesterol (Hypercholesterolaemia).

These medicines may be affected by CRESEMBA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CRESEMBA.

4. How do I use CRESEMBA?

How much to use

- Follow the instructions provided and use CRESEMBA until your doctor tells you to stop.
- Your doctor will tell you how much to take during the loading and maintenance phase.
- CRESEMBA needs to be taken regularly to be effective.

Adults

- The usual dose of CRESEMBA Capsules in adults is 200 mg (2 capsules) every 8 hours for 6 doses (First 48 hours - Starting Dose). Then 200 mg (2 capsules) ONCE daily thereafter (Usual Dose).

CRESEMBA can be taken with or without food.

CRESEMBA capsules should be swallowed whole with a full glass of water. Do not chew, crush, dissolve or open the capsules.

- The usual dose of CRESEMBA IV Injection in adults is 200 mg (1 reconstituted vial, diluted further for IV infusion) every 8 hours for 6 doses (First 48 hours - Starting Dose). Then 200 mg (1 reconstituted vial, diluted further for IV infusion) ONCE daily thereafter (Usual Dose).

CRESEMBA IV Injection will be given to you under close medical supervision.

CRESEMBA IV Injection is given as a slow injection into a vein (intravenous infusion). It must only be given by a doctor or trained nurse. It is a powder which is mixed with sterile water for injections and diluted further by your pharmacist, nurse or doctor.

When to use CRESEMBA and for how long

- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- The length of time you take CRESEMBA will depend on the type of infection you have.

- If you have weakened immune system or a difficult infection, you may need to be on CRESEMBA for longer periods of time (maybe longer than 6 months).
- Your doctor may switch you from CRESEMBA IV Injection to CRESEMBA Capsules once your condition improves.
- Continue taking CRESEMBA for as long as your doctor tells you. Do not stop taking CRESEMBA because you are feeling better.
- If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you forget to use CRESEMBA

CRESEMBA should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If you use too much CRESEMBA

If you think that you have used too much CRESEMBA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include: headache, feeling dizzy, restless or sleepy, tingling, reduced sense of touch or sensation in the mouth, problems being aware of things, 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.

5. What should I know while using CRESEMBA?

Things you should do

- Remind any doctor or dentist you visit that you are using CRESEMBA.
- Make sure you follow your doctor's instructions and keep all appointments, including blood tests.

Your doctor should monitor the function of your liver and kidneys using blood tests.

- If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

- If you are about to be started on any medicine, remind your doctor and pharmacists who treat you that you are taking CRESEMBA.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if:

- You develop a rash or blisters, swelling of your lips, mouth, tongue or throat with difficulty breathing - these may be signs of an allergic reaction while taking CRESEMBA.
- the symptoms of your infection do not improve within few days or if they become worse.

Things you should not do

- Do not stop using CRESEMBA or lower the dosage without checking with your doctor.
- Do not take CRESEMBA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- If you stop taking it suddenly or not complete the course as prescribed by your doctor, your condition may worsen or your symptoms may return.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CRESEMBA affects you.

This medicine may cause confusion, tiredness and sleepiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Capsules:

Keep your capsules in the original pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Store away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

IV injection

CRESEMBA IV Injection will be stored in the pharmacy or on the hospital ward. It is kept in a refrigerator where the temperature stays between 2-8°C.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related problems: <ul style="list-style-type: none">● feeling sick (nausea)● being sick (vomiting)● diarrhoea● stomach pain● decreased appetite	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● feeling bloated (abdominal distension) ● indigestion ● constipation ● changes in taste (dysgeusia) <p>Aches and pains:</p> <ul style="list-style-type: none"> ● headache ● back pain <p>Heart and related effects:</p> <ul style="list-style-type: none"> ● heartbeat problems - may be too fast or uneven, or extra heart beats – this may show in your heart tracing (electrocardiogram or ECG) ● inflamed veins that could lead to blood clots <p>Altered mental state:</p> <ul style="list-style-type: none"> ● hallucinations (delirium) ● depression ● difficulty sleeping ● fainting or feeling faint, dizziness 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● sensation of tingling, tickling, or prickling of the skin (paraesthesia) ● altered mental state (encephalopathy) ● feeling of ‘spinning’ or being dizzy (vertigo) ● feeling weak, very tired, or sleepy or generally out of sorts (malaise) <p>Skin and hair effects:</p> <ul style="list-style-type: none"> ● rash, itching ● problems with the skin, red or purple spots on the skin (petechiae) ● inflamed skin (dermatitis) ● hair loss <p>Changes in body detected in blood tests or other medical exams:</p> <ul style="list-style-type: none"> ● low potassium in your blood, ● low blood levels of magnesium, ● changes in blood tests of liver function 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● reduced white blood cells - can increase your risk of infection and fever ● reduced blood cells called 'platelets' - can increase your risk for bleeding or bruising ● reduced red blood cells - can make you feel weak or short of breath or make your skin pale ● severe reduction in blood cells - can make you feel weak, cause bruising or make infections more likely ● low blood sugar levels ● low levels in the blood of a protein called 'albumin' ● kidney failure ● inflammation or enlargement of the liver ● not getting the right goodness from your diet (malnutrition) ● problems with the blood circulation 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • low blood pressure 	

Serious side effects

Serious side effects	What to do
<p>Hypersensitivity reactions:</p> <ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • sudden and severe difficulty breathing • fainting, confusion, seizures or fits • sudden or severe itching, skin rash, hives or blisters • signs of kidney failure such as tiredness, lack of appetite and reduced or greatly increased amount of urine • chest pain 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CRESEMBA contains

Active ingredient (main ingredient)	<u>CRESEMBA capsules:</u> CRESEMBA Capsules contain 100 mg of isavuconazole (as 186.3 mg isavuconazonium sulfate)
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	<p><u>CRESEMBA Powder for Injection:</u></p> <p>CRESEMBA IV Injection contains 200 mg of isavuconazole (as 372.6 mg isavuconazonium sulfate)</p>
<p>Other ingredients (inactive ingredients)</p>	<p><u>CRESEMBA capsules:</u></p> <p>Contain the following other ingredients:</p> <p>Capsule Contents</p> <ul style="list-style-type: none"> ● magnesium citrate ● microcrystalline cellulose ● purified talc ● colloidal anhydrous silica ● stearic acid <p>Capsule Shell</p> <ul style="list-style-type: none"> ● hypromellose ● purified water ● iron oxide red (E172) (capsule body only) ● titanium dioxide (E171) ● gellan gum ● potassium acetate ● disodium edetate

- sodium lauryl sulfate

Printing Ink

- shellac
- propylene glycol
- potassium hydroxide
- iron oxide black (E172)

CRESEMBA Powder for Injection:

Contains the following other ingredients:

- mannitol
- sulfuric acid (for pH-adjustment)

Do not take this medicine if you are allergic to any of these ingredients.

What CRESEMBA looks like

CRESEMBA capsules (AUST R 305452):

CRESEMBA Capsules come in one strength, 100 mg

The capsules have a reddish-brown body marked with '100' in black ink and a white cap marked with "C" in black ink.

CRESEMBA Capsules 100 mg are available in cartons that contain 14 capsules.

Each carton contains 2 aluminium/aluminium blisters pack, with 7 capsules each.

Each capsule pocket is connected to a pocket that contains 'desiccant' to protect the capsule from moisture.

Do not puncture the blister containing the desiccant.

Do not swallow or use the desiccant.

CRESEMBA Powder for Injection (AUST R 305480):

CRESEMBA IV comes as a white to yellow powder in a clear glass vial with a rubber stopper and an aluminium cap with a plastic seal which contains 200 mg isavuconazole

Who distributes CRESEMBA

CRESEMBA is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

This leaflet was prepared in September 2022.