

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr CRESEMBA®

#### Isavuconazole Capsules

#### 40 mg isavuconazole (as isavuconazonium sulfate)

Read this carefully before you start taking **CRESEMBA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CRESEMBA**.

#### Serious Warnings and Precautions

CRESEMBA may cause harm to the fetus in a pregnant female.

If you are a female who can get pregnant you must use birth control while you are taking CRESEMBA. Contact your healthcare professional if you become pregnant while taking CRESEMBA.

See the section "Other warnings you should know about:" for additional information.

#### What is CRESEMBA used for?

CRESEMBA is used in children and adolescents from 6 to 18 years old to treat the following fungal infections:

- aspergillosis;
- mucormycosis (also called zygomycosis).

#### How does CRESEMBA work?

Isavuconazole works by killing or stopping the growth of the fungus which caused the infection.

#### What are the ingredients in CRESEMBA?

Medicinal ingredient: isavuconazonium sulfate.

Non-medicinal ingredients:

- **CRESEMBA (isavuconazole capsules, 40 mg):** *Contents:* magnesium citrate, microcrystalline cellulose, silica, stearic acid, talc; *Shell:* hypromellose, red iron oxide, titanium dioxide; *Printing ink:* black iron oxide, potassium hydroxide, propylene glycol, shellac.

#### CRESEMBA comes in the following dosage forms:

**Capsules:** 40 mg and 100 mg isavuconazole (as isavuconazonium sulfate)

**Powder for solution:** 200 mg/vial isavuconazole (as isavuconazonium sulfate)

**Do not use CRESEMBA if you:**

- are allergic to isavuconazonium sulfate or any of the other ingredients of this medicine. See What are the ingredients in CRESEMBA;
- have heartbeat problems called “familial short QT syndrome”;
- are taking any of the following medicines:
  - ketoconazole, used for fungal infections;
  - high doses of ritonavir, used for HIV;
  - rifampin or rifabutin, used for tuberculosis;
  - carbamazepine or phenytoin, used for epilepsy;
  - long-acting barbiturates (such as phenobarbital), used for epilepsy and sleep disorders;
  - St. John’s wort, a herbal medicine;
  - efavirenz or etravirine, used for HIV.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CRESEMBA. Talk about any health conditions or problems you may have, including if you:**

- have had an allergic reaction to other “azole” anti-fungal medicines in the past, such as ketoconazole, fluconazole, itraconazole, voriconazole, or posaconazole;
- have severe liver disease. Your doctor should monitor you for possible side effects. CRESEMBA can sometimes affect your liver function. Your doctor may carry out blood tests while you are taking this medicine.

**Other warnings you should know about:**

- Stop using CRESEMBA and tell your doctor immediately if you notice any of the following side effects: sudden wheezing, difficulty breathing, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest. These may be signs of a severe allergic reaction that may lead to death (anaphylaxis).
- CRESEMBA may cause harm to the fetus in a pregnant female. You must not take CRESEMBA while you are pregnant unless your healthcare professional advises you to. If you are a female who can get pregnant you must use birth control while you are taking CRESEMBA. Talk to your healthcare professional about effective forms of birth control. Tell your healthcare professional if you are pregnant or think you might be pregnant before taking CRESEMBA. While you are taking it, contact your healthcare professional if you become pregnant.
- Before you take CRESEMBA, tell your healthcare professional if you are breastfeeding or planning to breastfeed. You must not breastfeed a baby while you are taking CRESEMBA. This is because it can pass into your breast milk and may harm your baby.
- CRESEMBA may make you feel confused, tired or sleepy. It can also make you pass out. If this happens, do not drive or use machines.
- Tell your doctor immediately if you get severe blistering of the skin, mouth, eyes or genitals.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### Serious Drug Interactions

Do not take CRESEMBA if you are taking any of the following medicines:

- ketoconazole, used for fungal infections;
- high doses of ritonavir, used for HIV;
- rifampin or rifabutin, used for tuberculosis;
- carbamazepine or phenytoin, used for epilepsy;
- long-acting barbiturates (such as phenobarbital), used for epilepsy and sleep disorders;
- St. John's wort, a herbal medicine;
- efavirenz or etravirine, used for HIV.

**Unless your health professional tells you otherwise, do not take CRESEMBA if you are taking:**

- 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;
- pioglitazone, used for diabetes.

**Other drugs may interact with CRESEMBA. If you are taking any of the following medicines, your health care professional may need to adjust your dose or monitor you to check that the medicines are still having the desired effect:**

- cyclosporin, tacrolimus and sirolimus, used to prevent rejection of a transplant;
- cyclophosphamide, 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, amprenavir, nelfinavir, indinavir, delavirdine, nevirapine, lopinavir/ritonavir combination, used for HIV;
- alfentanil, fentanyl, used against strong pain;
- vincristine, vinblastine, used for cancer;
- mycophenolate mofetil (MMF), used in transplant patients;
- midazolam, used for severe insomnia and stress;
- bupropion, used for depression;
- metformin, used for diabetes;
- daunorubicin, doxorubicin, imatinib, irinotecan, lapatinib, mitoxantrone, topotecan, used for different sorts of cancer;
- atorvastatin, simvastatin, lovastatin, pravastatin, cilastatin, rosuvastatin, used to treat high cholesterol.

**How to take CRESEMBA:**

- Always take CRESEMBA exactly as your healthcare professional has told you to.
- Swallow capsules whole with water. Do not chew, crush, dissolve, or open the capsules.
- You can take CRESEMBA with or without food.

- 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.
- If you have a bodyweight less than 16 kg or you are not able to swallow the capsules, another form of this medicine may be suitable for you; ask your doctor or pharmacist.
- You will take CRESEMBA for as long as your healthcare professional determines is needed to clear your infection. Information on use for longer than 6 months is limited.

**Usual dose:**

The recommended dose for children and adolescents from 6 to 18 years is as follows:

	<b>Starting dose for the first two days (every 8 hours for 48 hours)</b>	<b>Usual Dose after the first two days (once a day)<sup>1</sup></b>
<b>Children and adolescents from 6 year to 18 years</b>		
Body weight 16 kg to < 18 kg	Two 40 mg capsules (80 mg) orally	Two 40 mg capsules (80 mg) orally
Body weight 18 kg to < 25 kg	Three 40 mg capsules (120 mg) orally	Three 40 mg capsules (120 mg) orally
Body weight 25 kg to < 32 kg	Four 40 mg capsules (160 mg) orally	Four 40 mg capsules (160 mg) orally
Body weight ≥ 32 kg	Five 40 mg capsules (200 mg) orally	Five 40 mg capsules (200 mg) orally

<sup>1</sup> This is started 12 to 24 hours after your last starting dose

**Overdose:**

If you think you have been given too much CRESEMBA, talk to your healthcare professional straight away. You may have side effects such as:

- 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, diarrhea, vomiting, feeling your heart beat, faster heart rate, being more sensitive to light.

If you think you, or a person you are caring for, have taken too much CRESEMBA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take CRESEMBA, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Never take a double dose to make up for a missed dose.

**What are possible side effects from using CRESEMBA?**

These are not all the possible side effects you may have when taking CRESEMBA. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of CRESEMBA include:

- nausea;
- vomiting;
- diarrhea;
- headache;
- change in the level of a liver enzyme in your blood;
- constipation;
- cough;
- swelling of arms or legs;
- back pain.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON (occurring in 1 in 100 to less than 1 in 10 patients)</b>			
Low potassium in your blood (constipation, feeling of skipped heart beats or palpitations, fatigue, muscle weakness or spasms, tingling or numbness).	✓		
<b>UNCOMMON (occurring in 1 in 1000 to less than 1 in 100 patients)</b>			
Blood problems, including decreased white blood cells, and other blood cell types, with symptoms such as increased infection, fever, bleeding, bruising.		✓	
Heart problems such as very slow, fast or irregular heartbeat or palpitations.		✓	
Liver problems: changes in blood tests of liver function, pain or swelling in the right upper stomach area, fever, fatigue, weakness, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine, pale stool, mental disorientation or confusion, sleepiness, loss of consciousness.		✓	
<b>UNKNOWN</b>			
Severe allergic reactions (anaphylaxis) such as sudden wheezing, breathing problems, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store at room temperature (15 - 30 °C). Store in the original packaging in order to protect from moisture.

Keep out of reach and sight of children.

### **If you want more information about CRESEMBA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.avirpharma.com](http://www.avirpharma.com)), or by calling 1-888-430-0436.

This leaflet was prepared by:

**AVIR Pharma Inc.**  
660 Boul. Industriel  
Blainville, Quebec  
J7C 3V4  
[www.avirpharma.com](http://www.avirpharma.com)

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## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr CRESEMBA®

#### Isavuconazole Capsules

100 mg isavuconazole (as isavuconazonium sulfate)

Read this carefully before you start taking **CRESEMBA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CRESEMBA**.

#### Serious Warnings and Precautions

CRESEMBA may cause harm to the fetus in a pregnant female.

If you are a female who can get pregnant you must use birth control while you are taking CRESEMBA. Contact your healthcare professional if you become pregnant while taking CRESEMBA.

See the section "Other warnings you should know about:" for additional information.

#### What is CRESEMBA used for?

CRESEMBA is used in adults to treat the following fungal infections:

- aspergillosis;
- mucormycosis (also called zygomycosis).

#### How does CRESEMBA work?

Isavuconazole works by killing or stopping the growth of the fungus which caused the infection.

#### What are the ingredients in CRESEMBA?

Medicinal ingredient: isavuconazonium sulfate.

Non-medicinal ingredients:

- **CRESEMBA (isavuconazole capsules, 100 mg):** *Contents:* magnesium citrate, microcrystalline cellulose, silica, stearic acid, talc; *Shell:* disodium edetate, gellan gum, hypromellose, potassium acetate, red iron oxide, sodium lauryl sulfate, titanium dioxide; *Printing ink:* black iron oxide, potassium hydroxide, propylene glycol, shellac.

#### CRESEMBA comes in the following dosage forms:

**Capsules:** 40 mg and 100 mg isavuconazole (as isavuconazonium sulfate)

**Powder for solution:** 200 mg/vial isavuconazole (as isavuconazonium sulfate)

**Do not use CRESEMBA if you:**

- are allergic to isavuconazonium sulfate or any of the other ingredients of this medicine. See What are the ingredients in CRESEMBA;
- have heartbeat problems called “familial short QT syndrome”;
- are taking any of the following medicines:
  - ketoconazole, used for fungal infections;
  - high doses of ritonavir, used for HIV;
  - rifampin or rifabutin, used for tuberculosis;
  - carbamazepine or phenytoin, used for epilepsy;
  - long-acting barbiturates (such as phenobarbital), used for epilepsy and sleep disorders;
  - St. John’s wort, a herbal medicine;
  - efavirenz or etravirine, used for HIV.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CRESEMBA. Talk about any health conditions or problems you may have, including if you:**

- have had an allergic reaction to other “azole” anti-fungal medicines in the past, such as ketoconazole, fluconazole, itraconazole, voriconazole, or posaconazole;
- have severe liver disease. Your doctor should monitor you for possible side effects. CRESEMBA can sometimes affect your liver function. Your doctor may carry out blood tests while you are taking this medicine.

**Other warnings you should know about:**

- Stop using CRESEMBA and tell your doctor immediately if you notice any of the following side effects: sudden wheezing, difficulty breathing, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest. These may be signs of a severe allergic reaction that may lead to death (anaphylaxis).
- CRESEMBA may cause harm to the fetus in a pregnant female. You must not take CRESEMBA while you are pregnant unless your healthcare professional advises you to. If you are a female who can get pregnant you must use birth control while you are taking CRESEMBA. Talk to your healthcare professional about effective forms of birth control. Tell your healthcare professional if you are pregnant or think you might be pregnant before taking CRESEMBA. While you are taking it, contact your healthcare professional if you become pregnant.
- Before you take CRESEMBA, tell your healthcare professional if you are breastfeeding or planning to breastfeed. You must not breastfeed a baby while you are taking CRESEMBA. This is because it can pass into your breast milk and may harm your baby.
- CRESEMBA may make you feel confused, tired or sleepy. It can also make you pass out. If this happens, do not drive or use machines.
- Tell your doctor immediately if you get severe blistering of the skin, mouth, eyes or genitals.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**



### Serious Drug Interactions

Do not take CRESEMBA if you are taking any of the following medicines:

- ketoconazole, used for fungal infections;
- high doses of ritonavir, used for HIV;
- rifampin or rifabutin, used for tuberculosis;
- carbamazepine or phenytoin, used for epilepsy;
- long-acting barbiturates (such as phenobarbital), used for epilepsy and sleep disorders;
- St. John's wort, a herbal medicine;
- efavirenz or etravirine, used for HIV.

**Unless your health professional tells you otherwise, do not take CRESEMBA if you are taking:**

- 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;
- pioglitazone, used for diabetes.

**Other drugs may interact with CRESEMBA. If you are taking any of the following medicines, your health care professional may need to adjust your dose or monitor you to check that the medicines are still having the desired effect:**

- cyclosporin, tacrolimus and sirolimus, used to prevent rejection of a transplant;
- cyclophosphamide, 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, amprenavir, nelfinavir, indinavir, delavirdine, nevirapine, lopinavir/ritonavir combination, used for HIV;
- alfentanil, fentanyl, used against strong pain;
- vincristine, vinblastine, used for cancer;
- mycophenolate mofetil (MMF), used in transplant patients;
- midazolam, used for severe insomnia and stress;
- bupropion, used for depression;
- metformin, used for diabetes;
- daunorubicin, doxorubicin, imatinib, irinotecan, lapatinib, mitoxantrone, topotecan, used for different sorts of cancer;
- atorvastatin, simvastatin, lovastatin, pravastatin, cilastatin, rosuvastatin, used to treat high cholesterol.

**How to take CRESEMBA:**

- Always take CRESEMBA exactly as your healthcare professional has told you to.
- Swallow capsules whole with water. Do not chew, crush, dissolve, or open the capsules.
- You can take CRESEMBA with or without food. 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.

- You will take CRESEMBA for as long as your healthcare professional determines is needed to clear your infection. Information on use longer than 6 months is limited.

**Usual dose:**

The recommended dose for adults is as follows:

	<b>Starting dose for the first two days (every 8 hours for 48 hours)</b>	<b>Usual Dose after the first two days (once a day)<sup>1</sup></b>
<b>Adults</b>	Two 100 mg capsules orally	Two 100 mg capsules orally

<sup>1</sup> This is started 12 to 24 hours after your last starting dose

**Overdose:**

If you think you have been given too much CRESEMBA, talk to your healthcare professional straight away. You may have side effects such as:

- 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, diarrhea, vomiting, feeling your heart beat, faster heart rate, being more sensitive to light.

If you think you, or a person you are caring for, have taken too much CRESEMBA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take CRESEMBA, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Never take a double dose to make up for a missed dose.

**What are possible side effects from using CRESEMBA?**

These are not all the possible side effects you may have when taking CRESEMBA. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of CRESEMBA include:

- nausea;
- vomiting;
- diarrhea;
- headache;
- change in the level of a liver enzyme in your blood;
- constipation;
- cough;
- swelling of arms or legs;
- back pain.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON (occurring in 1 in 100 to less than 1 in 10 patients)</b>			
Low potassium in your blood (constipation, feeling of skipped heart beats or palpitations, fatigue, muscle weakness or spasms, tingling or numbness).	✓		
<b>UNCOMMON (occurring in 1 in 1000 to less than 1 in 100 patients)</b>			
Blood problems, including decreased white blood cells, and other blood cell types, with symptoms such as increased infection, fever, bleeding, bruising.		✓	
Heart problems such as very slow, fast or irregular heartbeat or palpitations.		✓	
Liver problems: changes in blood tests of liver function, pain or swelling in the right upper stomach area, fever, fatigue, weakness, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine, pale stool, mental disorientation or confusion, sleepiness, loss of consciousness.		✓	
<b>UNKNOWN</b>			
Severe allergic reactions (anaphylaxis) such as sudden wheezing, breathing problems, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store at room temperature (15 - 30 °C). Store in the original packaging in order to protect from moisture.

Keep out of reach and sight of children.

### **If you want more information about CRESEMBA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.avirpharma.com](http://www.avirpharma.com)), or by calling 1-888-430-0436.

This leaflet was prepared by:

**AVIR Pharma Inc.**  
660 Boul. Industriel  
Blainville, Quebec  
J7C 3V4  
[www.avirpharma.com](http://www.avirpharma.com)

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## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr CRESEMBA®

#### **Isavuconazole for injection 200 mg/vial isavuconazole (as isavuconazonium sulfate)**

Read this carefully before you start taking **CRESEMBA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CRESEMBA**.

#### **Serious Warnings and Precautions**

CRESEMBA may cause harm to the fetus in a pregnant female.

If you are a female who can get pregnant you must use birth control while you are taking CRESEMBA. Contact your healthcare professional if you become pregnant while taking CRESEMBA.

See the section “Other warnings you should know about:” for additional information.

#### **What is CRESEMBA used for?**

CRESEMBA is used in adults, children older than 1 year old and adolescents to treat the following fungal infections:

- aspergillosis;
- mucormycosis (also called zygomycosis).

#### **How does CRESEMBA work?**

Isavuconazole works by killing or stopping the growth of the fungus which caused the infection.

#### **What are the ingredients in CRESEMBA?**

Medicinal ingredient: isavuconazonium sulfate.

Non-medicinal ingredients:

- **CRESEMBA (isavuconazole for injection):** mannitol, sulfuric acid (for pH-adjustment).

#### **CRESEMBA comes in the following dosage forms:**

**Capsules:** 40 mg and 100 mg isavuconazole (as isavuconazonium sulfate)

**Powder for solution:** 200 mg/vial isavuconazole (as isavuconazonium sulfate)

#### **Do not use CRESEMBA if you:**

- are allergic to isavuconazonium sulfate or any of the other ingredients of this medicine. See What are the ingredients in CRESEMBA;
- have heartbeat problems called “familial short QT syndrome”;

- are taking any of the following medicines:
  - ketoconazole, used for fungal infections;
  - high doses of ritonavir, used for HIV;
  - rifampin or rifabutin, used for tuberculosis;
  - carbamazepine or phenytoin, used for epilepsy;
  - long-acting barbiturates (such as phenobarbital), used for epilepsy and sleep disorders;
  - St. John’s wort, a herbal medicine;
  - efavirenz or etravirine, used for HIV.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CRESEMBA. Talk about any health conditions or problems you may have, including if you:**

- have had an allergic reaction to other “azole” anti-fungal medicines in the past, such as ketoconazole, fluconazole, itraconazole, voriconazole, or posaconazole;
- have severe liver disease. Your doctor should monitor you for possible side effects. CRESEMBA can sometimes affect your liver function. Your doctor may carry out blood tests while you are taking this medicine.

**Other warnings you should know about:**

- Stop using CRESEMBA and tell your doctor immediately if you notice any of the following side effects: sudden wheezing, difficulty breathing, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest. These may be signs of a severe allergic reaction that may lead to death (anaphylaxis).
- CRESEMBA may cause harm to the fetus in a pregnant female. You must not take CRESEMBA while you are pregnant unless your healthcare professional advises you to. If you are a female who can get pregnant you must use birth control while you are taking CRESEMBA. Talk to your healthcare professional about effective forms of birth control. Tell your healthcare professional if you are pregnant or think you might be pregnant before taking CRESEMBA. While you are taking it, contact your healthcare professional if you become pregnant.
- Before you take CRESEMBA, tell your healthcare professional if you are breastfeeding or planning to breastfeed. You must not breastfeed a baby while you are taking CRESEMBA. This is because it can pass into your breast milk and may harm your baby.
- CRESEMBA may make you feel confused, tired or sleepy. It can also make you pass out. If this happens, do not drive or use machines.
- Tell your doctor immediately if you get severe blistering of the skin, mouth, eyes or genitals.
- If taking CRESEMBA (isavuconazole for injection) as an infusion (drip into a vein), tell your doctor straight away if you notice any of the following side effects: low blood pressure, feel short of breath, nausea, dizziness, headache, or tingling. Your doctor may decide to stop the infusion.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### Serious Drug Interactions

Do not take CRESEMBA if you are taking any of the following medicines:

- ketoconazole, used for fungal infections;
- high doses of ritonavir, used for HIV;
- rifampin or rifabutin, used for tuberculosis;
- carbamazepine or phenytoin, used for epilepsy;
- long-acting barbiturates (such as phenobarbital), used for epilepsy and sleep disorders;
- St. John's wort, a herbal medicine;
- efavirenz or etravirine, used for HIV.

**Unless your health professional tells you otherwise, do not take CRESEMBA if you are taking:**

- 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;
- pioglitazone, used for diabetes.

**Other drugs may interact with CRESEMBA. If you are taking any of the following medicines, your health care professional may need to adjust your dose or monitor you to check that the medicines are still having the desired effect:**

- cyclosporin, tacrolimus and sirolimus, used to prevent rejection of a transplant;
- cyclophosphamide, 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, amprenavir, nelfinavir, indinavir, delavirdine, nevirapine, lopinavir/ritonavir combination, used for HIV;
- alfentanil, fentanyl, used against strong pain;
- vincristine, vinblastine, used for cancer;
- mycophenolate mofetil (MMF), used in transplant patients;
- midazolam, used for severe insomnia and stress;
- bupropion, used for depression;
- metformin, used for diabetes;
- daunorubicin, doxorubicin, imatinib, irinotecan, lapatinib, mitoxantrone, topotecan, used for different sorts of cancer;
- atorvastatin, simvastatin, lovastatin, pravastatin, cilastatin, rosuvastatin, used to treat high cholesterol.

**How to take CRESEMBA:**

- CRESEMBA will be given to you by a healthcare professional.
- Your healthcare professional will make sure that CRESEMBA is prepared correctly before it is given to you.
- CRESEMBA comes as a powder. The powder will be dissolved in sterile water and further diluted before it is given. CRESEMBA will then be infused directly into your vein by a healthcare

professional.

- You will be given CRESEMBA for as long as your healthcare professional determines is needed to clear your infection. Information on use for longer than 6 months is limited.
- Follow all instructions given to you by your healthcare professional.

**Usual dose:**

CRESEMBA (isavuconazole for injection) will be given to you by a doctor or a nurse.

The recommended dose in children older than 1 year, adolescents and adults is as follows:

	<b>Starting dose for the first two days (every 8 hours for 48 hours)</b>	<b>Usual Dose after the first two days (once a day)<sup>1</sup></b>
<b>Children older than 1 year and adolescents</b>		
Body weight below 37 kg	5.4 mg/kg isavuconazole intravenously	5.4 mg/kg isavuconazole intravenously
Body weight from 37 kg	1 vial intravenously <sup>2</sup>	1 vial intravenously <sup>2</sup>
<b>Adults</b>	1 vial intravenously <sup>2</sup>	1 vial intravenously <sup>2</sup>

<sup>1</sup> This is started 12 to 24 hours after your last starting dose

<sup>2</sup> After reconstitution and dilution

**Overdose:**

If you think you have been given too much CRESEMBA, talk to your healthcare professional straight away. You may have side effects such as:

- 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, diarrhea, vomiting, feeling your heart beat, faster heart rate, being more sensitive to light.

If you think you, or a person you are caring for, have taken too much CRESEMBA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However, tell your doctor or nurse if you think that a dose has been forgotten.

**What are possible side effects from using CRESEMBA?**

These are not all the possible side effects you may have when taking CRESEMBA. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of CRESEMBA include:

- nausea;
- vomiting;



- diarrhea;
- headache;
- change in the level of a liver enzyme in your blood;
- constipation;
- cough;
- swelling of arms or legs;
- back pain.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON (occurring in 1 in 100 to less than 1 in 10 patients)</b>			
Low potassium in your blood (constipation, feeling of skipped heart beats or palpitations, fatigue, muscle weakness or spasms, tingling or numbness).	✓		
Infusion related reactions, including sudden shortness of breath, dizziness, chills, abnormal sensations such a “pins and needles” or numbness, nausea or headache.		✓	
<b>UNCOMMON (occurring in 1 in 1000 to less than 1 in 100 patients)</b>			
Blood problems, including decreased white blood cells, and other blood cell types, with symptoms such as increased infection, fever, bleeding, bruising.		✓	
Heart problems such as very slow, fast or irregular heartbeat or palpitations.		✓	
Liver problems: changes in blood tests of liver function, pain or swelling in the right upper stomach area, fever, fatigue, weakness, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine, pale stool, mental disorientation or confusion, sleepiness, loss of consciousness.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN</b>			
Severe allergic reactions (anaphylaxis) such as sudden wheezing, breathing problems, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

The healthcare professional will store the product under refrigeration (2°C - 8°C).

Keep out of reach and sight of children.

### If you want more information about CRESEMBA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.avirpharma.com](http://www.avirpharma.com)), or by calling 1-888-430-0436.

This leaflet was prepared by:

**AVIR Pharma Inc.**  
 660 Boul. Industriel  
 Blainville, Quebec  
 J7C 3V4  
[www.avirpharma.com](http://www.avirpharma.com)

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