

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

 **POSANOL®**

Posaconazole, Solution for Injection, Delayed-Release Tablets, Oral Suspension

Read this carefully before you start taking **POSANOL** 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 **POSANOL**.

Serious Warnings and Precautions

- **Drug Interactions:** Taking POSANOL with other medicines can cause serious side effects. Do **NOT** take POSANOL if you are taking any of the following:
 - ergot alkaloids, used to treat migraines
 - cisapride, used to treat stomach problems
 - pimozide, used to treat mental health problems
 - quinidine, used to treat irregular heartbeat
 - terfenadine and astemizole, used to treat allergies
 - certain statin medicines that lower cholesterol, such as atorvastatin, lovastatin, simvastatin
 - sirolimus, used in transplant patients

Avoid taking POSANOL with any of the following:

 - cimetidine, used to treat stomach problems
 - rifabutin, an antibiotic used to treat bacterial infections including tuberculosis
 - phenytoin, used to prevent seizures

If you are taking POSANOL with any of the following your healthcare professional may have to reduce your dose and monitor you closely:

 - cyclosporine or tacrolimus, used in transplant patients
 - vinca alkaloids, including vincristine, used to treat cancer
 - venetoclax, used to treat cancer
 - midazolam, used as a sedative to help you sleep
 - calcium channel blockers, used to treat high blood pressure

- **Heart Problems:** POSANOL can cause serious heart problems including problems with your heart rhythm. Tell a healthcare professional immediately if you have any of the following symptoms while you are being treated with POSANOL:
 - very slow, fast or irregular heartbeat
 - shortness of breath
 - light-headedness
 - fainting
- **Liver Problems (including Liver Failure):** POSANOL can cause serious liver problems including liver failure. Your healthcare professional will do blood tests to see how well your liver is working before you start treatment with POSANOL and while you are being treated. Tell a healthcare professional immediately if you have any of the following symptoms while you are being treated with POSANOL:
 - dark colored urine
 - pale stools
 - yellowing of the skin and eyes
 - abdominal pain
 - nausea and vomiting

What is POSANOL used for?

- POSANOL Solution for Injection, Delayed-Release Tablets and Oral Suspension are used:

- to prevent fungal infections caused by the fungi *Aspergillus* and *Candida* in patients whose immune systems may be weakened due to other medicines or diseases.
 - to treat fungal infections caused by *Aspergillus* that have not improved during treatment with the anti-fungal medicines amphotericin B or itraconazole or in patients who cannot tolerate these medicines.
- POSANOL Oral Suspension can also be used to treat fungal infections in the mouth or throat area known as “thrush”, caused by *Candida*.
 - POSANOL Solution for Injection can be used in patients 18 years of age and older.
 - POSANOL Delayed-Release Tablets and Oral Suspension can be used in patients 13 years of age and older.

How does POSANOL work?

POSANOL belongs to a group of medicines called triazole antifungal agents. POSANOL works by killing or stopping the growth of some types of fungi that can cause infections in humans.

What are the ingredients in POSANOL?

Medicinal ingredients: Posaconazole

Non-medicinal ingredients:

POSANOL Solution for Injection: Betadex Sulfobutyl Ether Sodium (SBECD), edetate disodium, hydrochloric acid, sodium hydroxide, and water for injection.

POSANOL Delayed-Release Tablets: Croscarmellose sodium, hydroxypropylcellulose, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, Opadry† II Yellow [consists of the following ingredients: polyvinyl alcohol partially hydrolyzed, Macrogol/PEG 3350 (polyethylene glycol 3350), titanium dioxide, talc, and iron oxide yellow], and silicon dioxide.

POSANOL Oral Suspension: Artificial cherry flavor, citric acid monohydrate, glycerin, liquid glucose, polysorbate 80, purified water, simethicone, sodium benzoate, sodium citrate dihydrate, titanium dioxide, and xanthan gum.

POSANOL comes in the following dosage forms:

POSANOL Solution for Injection: 300 mg / vial (18 mg / mL)

POSANOL Delayed-Release Tablets: 100 mg

POSANOL Oral Suspension: 40 mg / mL

Do not use POSANOL® if:

- you are hypersensitive (allergic) to posaconazole or to any of the other ingredients in POSANOL (see **What are the ingredients in POSANOL?** section).
- you are taking any of the following medicines:
 - ergot alkaloids, used to treat migraines
 - cisapride, used to treat stomach problems
 - pimozone, used to treat mental health problems

- quinidine, used to treat irregular heartbeat
- terfenadine and astemizole, used to treat allergies
- certain statin medicines that lower cholesterol, such as atorvastatin, lovastatin, simvastatin
- sirolimus, used in transplant patients

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

- have had an allergic reaction to other antifungal medicines such as ketoconazole, fluconazole, itraconazole or voriconazole.
- are taking certain medicines that suppress your immune system such as cyclosporine and tacrolimus. Serious side effects that have been fatal, have happened in patients taking cyclosporine in combination with POSANOL. Your healthcare professional may adjust your dose of these immune suppressants and monitor their blood levels if you are taking them with POSANOL.
- are taking certain medicines used to treat cancer such as venetoclax and vincristine. Toxicity from vincristine has happened in patients taking it in combination with POSANOL. This has caused serious side effects such as:
 - Damage to nervous tissue
 - Seizures
 - Numbness, pain and weakness in hand and feet due to damage to nerves
 - Muscles cramps, nausea, vomiting and confusion due to water retention in body
 - Blockage of the intestine (abdominal pain).
- have or have had liver problems.
have kidney problems.
- have a history of heart problems, including heart failure, an irregular heartbeat, a slow heartbeat or a genetic condition called “congenital or acquired QT prolongation”.
- have problems with your electrolytes (low levels of potassium, magnesium or calcium in your blood).
- suffer from excessive vomiting or diarrhea.
- are breastfeeding. Do not breastfeed while being treated with POSANOL unless you have discussed the risks and benefits with your healthcare professional.
- are pregnant or planning on becoming pregnant. Do not use POSANOL during pregnancy unless you have discussed the risks and benefits with your healthcare professional. If you are a woman who could become pregnant, you must use effective birth control while you are being treated with POSANOL. Tell your healthcare professional immediately if you become pregnant while being treated with POSANOL.
- have galactose intolerance or glucose-galactose malabsorption. POSANOL Oral-Suspension contains glucose.

Other warnings you should know about:

Blood tests: POSANOL can cause abnormal blood test results. Your healthcare professional may ask you to have blood tests while you are being-treated with POSANOL.

Driving and using machines: Do not drive or operate machinery if you experience sleepiness or blurred vision.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following medicines **must not be taken** with POSANOL:

- cisapride, used to treat stomach problems
- pimozide, used to treat mental health problems
- quinidine, used to treat irregular heartbeat
- ergot alkaloids, used to treat migraines
- terfenadine and astemizole, used to treat allergies
- certain statin medicines that lower cholesterol, such as atorvastatin, lovastatin, simvastatin
- sirolimus, used in transplant patients

The following may interact with POSANOL:

- rifabutin or rifampin, antibiotics used to treat bacterial infections like tuberculosis
- phenytoin, used to prevent seizures
- cimetidine and metoclopramide, used to treat stomach problems – (only if you are being treated with POSANOL Oral Suspension)
- proton pump inhibitors, such as esomeprazole – (only if you are being treated with POSANOL Oral Suspension)
- efavirenz, fosamprenavir, atazanavir and atazanavir/ritonavir, used to treat HIV infection
- vinca alkaloids, including vincristine, used to treat cancer
- venetoclax, used to treat cancer
- cyclosporine and tacrolimus, used in transplant patients
- midazolam, used as a sedative to help you sleep
- statins, used to treat high cholesterol
- calcium channel blockers, used to treat high blood pressure
- digoxin, used to treat heart failure

How to take POSANOL:

- POSANOL must only be used as directed by your healthcare professional.
- Your healthcare professional will decide how long you are to be treated with POSANOL and your dose depending on your condition and how you respond to treatment.
- Do not stop treatment early because your infection may not be fully cured. Even if you feel well, your immune system may still be weakened and you may still need treatment to prevent an infection.
- Do not switch between POSANOL Delayed-Release Tablets and POSANOL Oral Suspension without talking to your healthcare professional. The dosing is different for the 2 formulations.
- If you are being treated with POSANOL Solution for Injection:
 - It will be given to you by a healthcare professional directly into your vein (IV).
- If you are being treated with POSANOL Delayed-Release Tablets:
 - POSANOL Delayed-Release Tablets can be taken with or without food.
 - POSANOL Delayed-Release Tablets must be swallowed whole. Use plenty of water if you have some difficulty swallowing.
 - Do not crush, chew, break, or dissolve the tablets.
- If you are being treated with POSANOL Oral Suspension:
 - Shake POSANOL Oral Suspension well before each use.

- Take POSANOL Oral Suspension with a meal or with a nutritional supplement if you are unable to eat a full meal.

Usual dose:

POSANOL Solution for Injection:

- You will be given 300 mg twice on the first day.
- After the first day you will be given 300 mg once a day.

POSANOL Delayed-Release Tablets:

- Take 300 mg (three 100 mg tablets) twice on the first day.
- After the first day take 300 mg (three 100 mg tablets) once a day.

POSANOL Oral Suspension:

Indication	Dose
Prevention of Fungal Infections	Take 200 mg (one 5 mL spoonful) three times a day with food or nutritional supplement.
Treatment of Fungal Infections Not Treated by Other Medicines	Take 400 mg (two 5 mL spoonfuls) twice a day with food or with a nutritional supplement. If you are not able to take food or nutritional supplement, your healthcare professional will tell you to take 200 mg (one 5 mL spoonful) four times a day.
Initial Treatment of Thrush	Take 100 mg (2.5 mL) twice on the first day. After the first day, take 100 mg (2.5 mL) once a day. Always take with food or nutritional supplement.

Overdose:

Take your bottle of POSANOL with you.

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

Missed Dose:

If you miss taking a dose of POSANOL, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for the forgotten dose.

What are possible side effects from using POSANOL?

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

Side effects may include:

- diarrhea
- gas

- nausea, vomiting
- stomach pain
- loss of appetite
- abnormal taste in the mouth
- dry mouth
- swelling in the mouth
- headache
- dizziness
- numbness or tingling
- sleepiness, tiredness
- weakness
- rash
- cough, shortness of breath

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	
COMMON			
Anemia (low red blood cells): shortness of breath, feeling very tired, pale skin, fast heartbeat, loss of energy, or weakness.		✓	
Neutropenia (low white blood cells): infections (fever, chills, sore throat, mouth sores), weakness, fatigue, aches and pains, and flu-like symptoms.		✓	
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness, nosebleeds, tiny red spots on the skin.		✓	
Electrolyte imbalance (low levels of potassium, magnesium or calcium in your blood): weakness, fatigue, muscle cramps.		✓	
Edema: swelling of the hands or feet.	✓		
UNCOMMON			
Heart problems: very slow, fast or irregular heartbeat, shortness of breath, light-headedness, fainting.			✓

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	
RARE			
Allergic reaction: severe skin blistering, peeling, rash, swollen lips, mouth and throat, difficulty in breathing.			✓
Liver problems (including liver failure): dark colored urine, pale stools, yellowing of the skin and eyes, abdominal pain, nausea, vomiting.			✓

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.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: Keep out of the reach and sight of children. Do not use this product after the expiry date stated on the label.

POSANOL Solution for Injection:

Your healthcare professional will store POSANOL Solution for Injection.

POSANOL Delayed-Release Tablets:

Store at room temperature (15 to 30°C).

POSANOL Oral Suspension:

Store at room temperature (15 to 30°C). Do not freeze. Once opened, use the suspension within 4 weeks.

If you want more information about POSANOL:

- 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.merck.ca, or by calling 1-800-567-2594.

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