

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

CORVERT[®] **(ibutilide fumarate injection)**

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

CORVERT is intended for use only in patients with life-threatening irregular heartbeats (arrhythmias). Most anti-arrhythmic drugs have the potential to cause dangerous arrhythmias; some have been shown to be associated with an increase of sudden death. Your doctor will tell you about the risk and benefits of anti-arrhythmic therapy.

What is CORVERT used for?

CORVERT is used to restore a normal heart rhythm in adults with certain types of abnormal heart rhythm (arrhythmias):

- atrial fibrillation or
- atrial flutter

It is unknown how safe or effective CORVERT is for use in children.

How does CORVERT work?

CORVERT works to restore a normal heart rhythm.

What are the ingredients in CORVERT?

Medicinal ingredients: Ibutilide fumarate

Non-medicinal ingredients: Sodium acetate trihydrate, sodium chloride, sodium hydroxide solution or hydrochloric acid solution (to adjust pH), and water for injection.

CORVERT comes in the following dosage forms:

Solution for injection: 0.1 mg / mL.

Do not use CORVERT if:

- you are allergic to any of the ingredients in CORVERT (see “**What are the ingredients in CORVERT?**” above).

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

- have low levels of potassium.
- have low levels of magnesium.
- have problems with your liver.
- have problems with your kidneys.
- have other heart problems.
- took a heart rhythm medication within 4 hours before you are going to be given CORVERT.

Other warnings you should know about:

Pregnancy, breastfeeding and women of childbearing age: You should not take CORVERT if you are:

- pregnant or planning to become pregnant. Your doctor will decide whether the benefit of giving you CORVERT outweighs the risk to your unborn baby. Tell your doctor if you become pregnant.
- breastfeeding or planning to breastfeed. CORVERT can pass into your breast milk.
- of childbearing age and are not using an effective and reliable method of birth control.

Laboratory Tests: CORVERT can cause abnormal blood test results for:

- Liver function tests
- Blood, Urea and Nitrogen (BUN) test
- Kidney function tests
- Tests to measure blood magnesium, potassium and sodium levels
- Tests to measure hemoglobin, platelets and white blood cell counts

Your doctor will decide when to perform blood tests and will interpret the results.

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

The following may interact with CORVERT:

- Other drugs used to treat abnormal heart rhythms, such as:
 - disopyramide,
 - quinidine,
 - procainamide,
 - amiodarone,
 - sotalol
- Drugs that prolong the QT interval. These include:
 - Psychoactive drugs, such as:
 - Phenothiazines
 - Tricyclic antidepressants

- Tetracyclic antidepressants
- Pimozide
- Drugs used to treat allergies (antihistamines) such as terfenadine and astemizole
- Drugs used to treat infections, particularly when erythromycin given through your vein (intravenously)
- Drugs to treat malaria (antimalarial) such as halofantrine
- Drugs used to treat gastrointestinal problems such as cisapride.

How CORVERT is given:

CORVERT will always be given to you:

- by a doctor or nurse
- as an injection into your vein as an infusion (intravenous infusion)
- in a place where there is continuous ECG monitoring and the proper equipment available to the doctor or nurse during and after treatment with CORVERT.

Usual dose:

Your doctor will determine the right dose of CORVERT for you based on your weight.

Overdose:

If you think you have been given too much CORVERT, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using CORVERT?

These are not all the possible side effects you may feel when taking CORVERT. You will be watched closely to check for serious side effects. Tell your caregiver if you feel short of breath or like you might pass out. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- slow heart beat
- high blood pressure
- headache
- constipation
- bladder infection
- fatigue
- increase in white blood cells
- leg cramps
- difficulty sleeping
- weakness
- lack of energy
- joint pain
- muscle pain
- itching

- swelling
- bruising
- inflammation of the veins
- difficulty urinating
- nausea
- vomiting
- diarrhea
- confusion
- trouble with your vision

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	
Allergic reaction: hives; difficulty breathing; swelling of face, lips, tongue, or throat			√
Chest pain, palpitations, irregular heartbeat		√	
Low blood pressure: fainting, dizziness			√
Tremor/abnormal involuntary movements			√

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

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • 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. <p><i>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.</i></p>
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Storage:

CORVERT will be stored by your healthcare professional.

Store:

- At room temperature (15 -30°C).
- In its original carton until it is used to protect it from light.

Keep out of reach and sight of children.

If you want more information about CORVERT:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<http://www.pfizer.ca>), Pfizer Canada ULC at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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