

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

**IVOZFO™**  
**fosfomycin for injection**

Read this carefully before you start taking **IVOZFO™**. 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 **IVOZFO™**.

**Serious Warnings and Precautions**

- IVOZFO™ contains sodium.
- Each gram of IVOZFO™ contains 320 mg of sodium. This is equal to 16 % of the recommended maximum daily dietary intake of sodium for an adult.
- Your doctor will be especially careful with this medicine if you are receiving more than 16 g of IVOZFO™ a day.
- Your doctor will monitor the electrolytes in your blood, including your sodium levels, while you are receiving IVOZFO™.
- Before you receive IVOZFO™, tell your doctor if you have any of the following health conditions: heart problems, high blood pressure, hyperaldosteronism which is a condition where you have too much of a hormone called aldosterone, cirrhosis (scar tissue) of the liver, kidney problems, high levels of sodium in your blood, or fluid in your lungs. .
- IVOZFO™ contains sodium that could make these conditions worse.

**What is IVOZFO™ used for?**

IVOZFO™ is used in adults and children to treat infections of the:

- lung
- bones
- kidney and bladder
- brain (called meningitis)
- blood that are caused by any of the infections listed above

It is used when other antibiotics cannot be used or have not worked.

This medicine is usually given in combination with other antibiotics.

Antibacterial drugs like IVOZFO™ treat only bacterial infections. They do not treat viral infections such as the common cold.

### **How does IVOZFO™ work?**

IVOZFO™ belongs to a group of medicines called antibiotics. It works by killing a type of germ called bacteria that causes serious infections.

### **What are the ingredients in IVOZFO™?**

Medicinal ingredients: fosfomicin sodium

Non-medicinal ingredients: succinic acid

IVOZFO™ does not contain any preservatives.

### **IVOZFO™ comes in the following dosage forms:**

As a powder for solution. It comes in vials containing 2g, 4 g or 8 g fosfomicin (as fosfomicin sodium).

### **Do not use IVOZFO™ if you are:**

- allergic to fosfomicin
- allergic to succinic acid, which is the non-medicinal ingredient in IVOZFO™
- allergic to any part of the container

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

- have heart problems
- have high blood pressure
- have hyperaldosteronism which is a condition where you have too much of a hormone called aldosterone
- high levels of sodium in your blood
- have too much fluid in your lungs which is a condition called pulmonary edema
- have kidney problems since your doctor may need to change the dose you receive
- have cirrhosis (scar tissue) of the liver
- are pregnant or thinking of becoming pregnant
- are breastfeeding or are planning to breastfeed

### **Other warnings you should know about:**

#### *Pregnancy and breastfeeding*

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this medicine. If you are pregnant, IVOZFO™ may pass to your baby in the womb. It may also pass to your baby through your breast milk. If you are pregnant or breastfeeding your doctor will decide if you can receive this medicine.

### *Sodium content*

Each gram of IVOZFO contains 320 mg sodium (salt). This is equal to 16 % of the recommended maximum daily dietary intake of sodium for an adult. Your doctor will monitor the electrolytes in your blood, including your sodium levels, while you are receiving IVOZFO™. You should be on a low sodium diet while you are receiving IVOZFO™.

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

### **How to take IVOZFO™:**

- IVOZFO™ will be given to you by a healthcare professional.
- Your healthcare professional will reconstitute and further dilute IVOZFO™ before giving it to you.
- It is usually given 2, 3 or 4 times a day.
- It will be infused directly into your vein.
- It will be infused over a period of 15 – 60 minutes, depending on the dose you are given.
- If you are at risk for low levels of potassium in your blood, the infusion might take up to 4 hours.
- Follow all instructions given to you by your healthcare professional.

### **Usual dose:**

- Your doctor will decide how much IVOZFO™ you will be given and how often and for how long you will receive it.
- The dose you are given will depend on the type and severity of your infection.
- If you have kidney problems or require dialysis, your dose may be reduced.
- For children, the dose they are given depends on their weight and age.

### **Overdose:**

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

### **Missed Dose:**

IVOZFO™ is administered by a healthcare professional. If you suspect a missed dose, talk to your healthcare professional.

### **What are possible side effects from using IVOZFO™?**

These are not all the possible side effects you may feel when taking IVOZFO™. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Nausea, retching, vomiting, stomach ache or mild diarrhea

- Taste disturbances
- Shortness of breath
- Rash
- Decreased appetite
- Headache
- Feeling of dizziness or a “spinning” sensation
- Tiredness
- Confusion
- Swelling due to fluid retention (edema)
- Visual impairment

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Hypokalemia</b> (low level of potassium in the blood): constipation, confusion, cramping, feeling of skipped heartbeat or palpitations, fatigue, trouble breathing, muscle weakness, muscle spasms or twitching.		√	
<b>Hypernatremia</b> (high level of sodium in the blood): coma, confusion, thirst, muscle twitches, seizure.		√	
Pain, burning, redness or swelling along the vein being used for infusion of this medicine		√	
<b>UNCOMMON</b>			
<b>Liver problems:</b> abdominal pain, dark urine, fatigue, light-coloured stool, loss of appetite, nausea, vomiting, yellowing of the skin or eyes (jaundice).		√	
<b>RARE</b>			
<b>Anemia</b> (decreased red blood cells): dizziness, feeling tired and weak, loss of energy, pale complexion, shortness of breath.		√	
<b>Eosinophilia</b> (increased numbers of certain white blood		√	

cells): abdominal pain, rash, weight loss, wheezing.			
<b>VERY RARE</b>			
<b>Allergic reaction:</b> difficulty breathing, difficulty swallowing, fever, hives, itchy skin, rash, swelling of your tongue, throat or face.		√	
<b>UNKNOWN</b>			
<b>Clostridium difficile colitis</b> (bowel inflammation): abdominal pain or tenderness, fever, severe diarrhea (bloody or watery).		√	
<b>Asthma attack or heart failure:</b> shortness of breath, wheezing or a tight feeling in the chest.		√	
<b>Tachycardia</b> (faster heart beat)		√	
<b>Neutropenia</b> (decreased white blood cells): aches, feeling tired, fever, flu-like symptoms, infections.		√	
<b>Thrombocytopenia</b> (decreased platelets in the blood): bleeding, bruising, fatigue, weakness.		√	
<b>Hypophosphatemia</b> (low level of phosphate in the blood): confusion, coma, fatigue, muscle weakness.		√	

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.

### 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 ([www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](http://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:**

- Keep out of the reach and sight of children.
- Store at 15-30°C.
- Do not use this medicine after the expiry date which is stated on the carton and label after “EXP”. The expiry date refers to the last day of that month.
- Following dilution into Dextrose 5% in Water, the product should be used immediately. If not used immediately, the diluted product should be protected from light and stored at 2-8°C or at 25°C in the PVC bags or at 2-8°C in the vial for no longer than 48 hours.

**If you want more information about IVOZFO™:**

- 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 [www.veritypharma.com](http://www.veritypharma.com), or by calling 1-888-877-4414.

This leaflet was prepared by Verity Pharmaceuticals.

Last Revised MAY-01-2019

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