

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ZAROXOLYN® Metolazone Tablets

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

What is ZAROXOLYN used for?

ZAROXOLYN is used in adults to:

- Treat swelling due to excess fluid in the body associated with heart and kidney diseases.
- Treat high blood pressure, either alone or with other medications.

How does ZAROXOLYN work?

ZAROXOLYN is a type of diuretic (water pill). It increases the amount of urine you make, which causes your body to get rid of excess fluid. This helps to decrease swelling and lowers your blood pressure.

What are the ingredients in ZAROXOLYN?

Medicinal ingredients: Metolazone
Non-medicinal ingredients: D&C Red #33 aluminum lake, magnesium stearate and microcrystalline cellulose.

ZAROXOLYN comes in the following dosage forms:

Tablets, 2.5 mg

Do not use ZAROXOLYN if:

- You have decreased urine production (anuria).
- You have severe liver disease affecting your brain function (hepatic coma or pre-coma).
- You are allergic to metolazone.

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

- Have diabetes.
- Have gout or had gout in the past.
- Have severe liver disease.
- Have severe kidney disease or are on dialysis.
- Have systemic lupus erythematosus.

- Are deficient in potassium.
- Are pregnant, think you are pregnant, or are planning to become pregnant.
- Are breastfeeding, or are planning to breastfeed.

Other warnings you should know about:

Check-Ups: Your healthcare professional may do blood tests during your treatment with ZAROXOLYN. These tests may be done to check your:

- Potassium levels.
- Blood urea nitrogen levels.
- Uric acid levels.
- Glucose levels.

Eye Disorders: Water pills such as ZAROXOLYN can cause sudden eye disorders such as:

- Choroidal effusion: an abnormal buildup of liquid in your eye that may result in vision changes.
- Myopia: sudden nearsightedness or blurred vision.
- Glaucoma: an increased pressure in your eyes, eye pain. May lead to permanent vision loss if untreated.

If your vision changes, stop taking ZAROXOLYN and seek medical help. These eye disorders are related and can develop within hours to weeks of starting ZAROXOLYN.

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 ZAROXOLYN:

- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications)
- Other medications used to treat high blood pressure (antihypertensives)
- Corticosteroids
- Muscle relaxants (curariform medications)
- Digitalis
- Medications used to treat gout
- Other medications used to treat swelling, such as furosemide and other loop diuretics
- Medications used to treat diabetes, such as insulin and oral antidiabetic agents
- Lithium, an antidepressant
- Methenamine, an antibiotic used to treat urinary tract infections
- Medications used to treat pain, fever and inflammation (salicylates and other nonsteroidal anti-inflammatory drugs (NSAIDs))
- Medications known as sympathomimetics

How to take ZAROXOLYN:

- Take ZAROXOLYN as prescribed by your healthcare professional.

Usual dose:

Swelling due to heart failure: 5 mg – 10 mg, once daily
 Swelling due to kidney disease: 5 mg – 20 mg, once daily
 High blood pressure: 2.5 mg – 5 mg, once daily

Overdose:

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

Missed Dose:

If you have forgotten to take your dose, carry on with the next dose at the usual time. Do not double the dose. Talk to your healthcare professional if you are unsure.

What are possible side effects from using ZAROXOLYN?

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

- Dizziness or lightheadedness
- Drowsiness
- Fatigue
- Weakness
- Impotence (not able to have an erection)
- Restlessness (sometimes resulting in being unable to sleep)
- Headache
- Chills
- Nausea
- Vomiting
- Pain in your upper abdomen
- Abdominal bloating
- Diarrhea
- Constipation
- Joint pain
- Muscle cramps or spasms
- Burning or prickling sensation in hands, arms, feet or legs

ZAROXOLYN can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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	
UNKNOWN FREQUENCY			

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	
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness			X
Anorexia (a type of eating disorder): loss of appetite, not eating even if you are hungry, rapid or severe weight loss		X	
Chest pain or discomfort			X
Depression with symptoms of psychosis, like hallucinations (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse		X	
Dehydration (dry mouth, excessive thirst): thirst, headache, loss of appetite, feel tired and weak, lack of sweating, decreased blood pressure and urine, dark yellow urine		X	
Electrolyte imbalance (low levels of potassium or sodium in the blood): weakness, drowsiness, muscle pain or cramps, irregular heartbeat		X	
Eye disorders: - Choroidal effusion (buildup of liquid in your eyes): blind spots, eye pain, blurred vision - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eye, eye pain		X	
Fainting			X

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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Gout: red, tender, hot, swollen joints, fever, generally feeling unwell, fast heart rate		X	
Hepatitis (Inflammation of liver): abdominal pain, fatigue, fever, itchiness, light coloured stool, trouble thinking clearly, yellowing of the skin		X	
Hyperglycemia: (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		X	
Hyperuricemia (high levels of uric acid in the blood): joint pain or stiffness, swelling, pain or aching in your lower back, side, abdomen, or groin, nausea		X	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		X	
Jaundice (build up of bilirubin in the blood): yellowing of the skin and eyes, dark urine, light coloured stool, itching all over your body		X	
Necrotizing vasculitis (inflammation of blood vessels under the skin or other tissues): chills, fever, skin discoloration		X	
Neuropathy (nerve damage/pain): muscle weakness, cramps, twitching, loss of feeling in body parts		X	
Palpitations: fluttering or pounding heart, heart is beating fast, skipping beats			X
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen		X	

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	
Skin disorders - Photosensitivity (sensitivity to sunlight): itchy, dry, red skin when exposed to sunlight - Purpura (bleeding under the skin): bruising, purple spots or patches on your skin - Urticaria (skin rash): rash, hives, itchy skin		X	
Stevens-Johnson syndrome (SJS) / Toxic Epidermal Necrolysis (TEN) (severe skin rashes): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			X
Venous thrombosis (blood clot in a vein): swelling and pain in one part of the body, usually in the legs			X
Vertigo (a sense of spinning dizziness)		X	

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 to 30 °C) and protect from light.

Keep out of reach and sight of children.

If you want more information about ZAROXOLYN:

- 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.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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