

PART III: CONSUMER INFORMATION

^{Pr} Eribulin Mesylate Injection Eribulin Mesylate Injection

This leaflet is part III of a three-part "Product Monograph" published when Eribulin Mesylate Injection was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Eribulin Mesylate Injection. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Eribulin Mesylate Injection is a cancer medicine. It is sold by prescription. It is used to treat:

- breast cancer that has spread to other parts of the body. It is used when you have had two or more cancer drug treatment plans to treat your breast cancer that has spread.

Eribulin Mesylate Injection is used to treat adult patients with a type of cancer that starts in fat cells called liposarcoma.

Eribulin Mesylate Injection is used if you:

- can't have an operation to take the cancer out and have liposarcoma that is advanced or has spread to other parts of the body. And,
- have had other drugs to treat this.

What it does:

Eribulin Mesylate Injection is an anti-cancer agent which works by stopping the growth of cancer cells.

When it should not be used:

Do not use Eribulin Mesylate Injection if you are allergic to eribulin mesylate, or halichondrin B, or any drug related to halichondrin B.

What the medicinal ingredient is:

Eribulin mesylate

What the non-medicinal ingredients are:

Dehydrated Alcohol/Ethanol hydroxide, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

What dosage forms it comes in:

Eribulin Mesylate Injection contains 1 mg eribulin mesylate per vial in 2 mL of solution and 1.5 mg eribulin mesylate per vial in 3mL.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Eribulin Mesylate Injection should be prescribed and managed by a doctor experienced in the use of cancer drugs. Serious side effects with Eribulin Mesylate Injection include:

- Neutropenia (decrease in the number of white blood cells)
- Abnormal electrical signal of the heart called "prolongation of the QT interval" (changes in heartbeat)
- Eribulin Mesylate Injection has not been studied in patients with severe hepatic (liver) impairment or End Stage Renal Disease (ESRD, a disease of the kidney).

BEFORE you use Eribulin Mesylate Injection talk to your doctor or pharmacist about all of your medical conditions, including if you:

- have low white blood cell counts or low platelet levels
- have a fever (temperature above 38.1°C) or an infection
- have heart problems including "prolongation of the QT interval"(changes in heartbeat)
- experience numbness, tingling or burning in your hands and feet
- have liver or kidney problems
- are pregnant or plan to become pregnant. You should not receive Eribulin Mesylate Injection during pregnancy because it may harm your unborn baby. Talk with your health professional about how to prevent pregnancy while receiving Eribulin Mesylate Injection, as you should use effective contraception during and for at least 3 months after receiving Eribulin Mesylate Injection. Tell your health professional right away if you become pregnant or think you are pregnant while receiving Eribulin Mesylate Injection
- are breast feeding. It is not known if Eribulin Mesylate Injection passes into breast milk. Breast feeding must be avoided.

Eribulin Mesylate Injection may cause drowsiness or tiredness. Do not drive or operate machinery until you know how the medication affects you.

The safety and effectiveness of Eribulin Mesylate Injection in patients under 18 years of age have not been established.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor before taking Eribulin Mesylate Injection if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Eribulin Mesylate Injection may interact with the following medications:

- drugs known to prolong the QT/QC interval and/or cause torsade de pointes
- drugs that decreases electrolyte levels

PROPER USE OF THIS MEDICATION

Usual dose: 1.4 mg / m² body surface area given as an injection into the vein over 2 to 5 minutes on Days 1 and 8 of a 21-day treatment cycle.

Overdose:

If you think you, or a person you are caring for, have taken too much Eribulin Mesylate Injection, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

Very common side effects

- low white or red blood cell count
- general weakness
- fever
- muscle or joint pain, bone pain
- headache
- decreased appetite
- weight loss
- shortness of breath
- cough
- blisters or sores of the inside of the mouth
- back pain

Common side effects

- dizziness, vertigo
- skin rash, itchiness
- high or low blood pressure
- anxiety, depression, trouble sleeping
- watery eyes
- dry mouth
- stomach upset, heartburn
- chills
- upper respiratory tract infections (cough, sore throat, runny nose)
- weight gain
- changed sense of taste
- numbness
- sore throat
- fast heart rate
- hoarse voice
- pain when passing urine
- sleepiness

Eribulin Mesylate Injection can cause abnormal blood test results. These include changes in bone marrow function tests (white blood cell count, red blood cell count and platelet count),

salt levels in the blood (including potassium, calcium, magnesium, phosphorus and sodium) liver enzymes (called AST, ALT and alkaline phosphatase), protein, bile pigment (bilirubin) and other blood tests such as blood sugar and lactate dehydrogenase (LDH). Your doctor will decide when to perform test 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	
VERY COMMON			
Tiredness	X		
Hair loss	X		
Nausea, vomiting, constipation	X		
Peripheral neuropathy: Numbness, tingling, or burning in hands and feet		X	
Diarrhea	X		
Urinary tract infection: fever, chills, burning, pain or difficulty urinating		X	
Peripheral edema: Swelling of hands, feet, or limbs		X	
Belly pain or bloating		X	
COMMON			
Febrile neutropenia: Infection (fever, chills, cough) when your white blood cell count is low.			X
Thrombocytopenia (low numbers of platelets that are in the blood. These cells help blood to clot): bruising or taking longer to stop bleeding.		X	
Muscle spasms or weakness		X	
Prolongation of the QT interval: Changed heart beat		X	
Dehydration: feeling thirsty, tired, lightheaded, dry mouth, dark coloured urine and passing urine less often than normal.		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	
Hyperglycaemia (high blood sugar): passing urine a lot, thirst and hunger.		X	
Pulmonary embolism (blood clot on the lung): chest pain, shortness of breath, coughing up blood.			X
UNCOMMON Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.		X	
Hepatotoxicity (liver damage): belly pain, yellowing of the skin or whites of the eyes, itching. Nausea, vomiting and loss of appetite.		X	
Renal failure (kidneys not working): causing tiredness, not passing urine, swelling in the legs, confusion.			X
Deep vein thrombosis (blood clot in the leg): pain, swelling, redness in the leg.		X	
RARE Pancreatitis (inflammation of the pancreas): severe pain in the upper part of the belly with nausea and vomiting.		X	
Disseminated intravascular coagulation (DIC): a serious disorder of blood clotting resulting in the widespread formation of blood clots and internal bleeding.			X
Sudden death			

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	
Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): any combination of red itchy rash with blisters and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals. It often goes with fever, chills, headache, cough, body aches or joint pain. You may have dark urine, yellow skin or eyes.			X
Atrial fibrillation (irregular heart beat): dizziness, palpitations, racing heartbeat.		X	
Pneumonia: productive cough, chest pain, difficulty breathing, fever.		X	
Sepsis that can lead to death: fever with a racing heartbeat, rapid shallow breathing, cold, pale, clammy or mottled skin and/or confusion.			X
UNKNOWN FREQUENCY Interstitial lung disease: Breathing problems including persistent cough and/or shortness of breath.		X	

This is not a complete list of side effects. For any unexpected effects while taking Eribulin Mesylate Injection, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C to 30°C. Do not freeze.

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

MORE INFORMATION

If you want more information about Eribulin Mesylate Injection:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website: www.marcanpharma.com, or by calling 1-855-627-2261.

This leaflet was prepared by Marcan Pharmaceuticals Inc.

Last Revised: 2026-01-09