

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

MELPHALAN FOR INJECTION

Read this carefully before you start taking **MELPHALAN FOR INJECTION** 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 **MELPHALAN FOR INJECTION**.

Serious Warnings and Precautions

MELPHALAN FOR INJECTION should only be prescribed by a healthcare professional experienced in the use of anti-cancer drugs.

The following serious side effects have been seen in patients taking MELPHALAN FOR INJECTION:

- **Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fast heartbeat.
- **Bone Marrow Suppression:** signs and symptoms of infections (including fever, chills, sore throat, mouth ulcers), fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin lips and nail beds.
- **Lung Problems Causing Death:** suddenly worsening shortness of breath, wheezing, tiredness, possibly with a cough or fever, painful breathing.
- **Infertility in both men and women.**
- **Birth defects in babies whose mother or father was taking MELPHALAN FOR INJECTION.**
- **Development of new cancers, other than the cancer you are being treated for.**

What is MELPHALAN FOR INJECTION used for?

MELPHALAN FOR INJECTION is used in adults:

- to relieve symptoms caused by multiple myeloma, a cancer of the blood
- to relieve symptoms caused by a type of ovarian cancer (epithelial carcinoma of the ovary) that cannot be removed by surgery
- together with surgery to treat skin cancer (malignant melanoma)

How does MELPHALAN FOR INJECTION work?

MELPHALAN FOR INJECTION belongs to a group of anti-cancer medicines called antineoplastic alkylating agents. These medications work by stopping cancer cells from dividing and growing.

What are the ingredients in MELPHALAN FOR INJECTION:

Medicinal ingredient: melphalan.

Non-medicinal ingredients: ethanol, hydrochloric acid (for pH control), povidone, propylene glycol, sodium citrate, water for injection.

MELPHALAN FOR INJECTION comes in the following dosage forms:

Lyophilized powder for Injection with diluent: 50 mg/vial.

Do not use MELPHALAN FOR INJECTION if:

- you are allergic to melphalan, chlorambucil or any of the other ingredients in MELPHALAN FOR INJECTION.
- your disease has not responded to MELPHALAN FOR INJECTION treatment.
- you are currently receiving or have recently received radiotherapy or chemotherapy.
- you have been recently treated with medicines similar to MELPHALAN FOR INJECTION.
- you have low neutrophil or platelet counts (neutrophils and platelets are blood cells).
- you are breastfeeding.

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

- are pregnant or likely to become pregnant.
- have recently been vaccinated, or are planning to be vaccinated with a live vaccine.
- have kidney disease.

Other warnings you should know about:

MELPHALAN FOR INJECTION has been reported to cause new cancers in some patients who have been treated with the drug. If you have any concerns or notice any new symptoms talk to your healthcare professional.

If you need surgery, tell the healthcare professional or anaesthetist that you are taking MELPHALAN FOR INJECTION.

Your healthcare professional will do blood tests before you start treatment with MELPHALAN FOR INJECTION and before each dose.

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 MELPHALAN FOR INJECTION:

- nalidixic acid, an antibiotic used to treat bacterial infections.
- cyclosporine, used to prevent organ rejection in people who have had an organ transplant.
- busulfan
- vaccination with live vaccines.

How to take MELPHALAN FOR INJECTION injection:

MELPHALAN FOR INJECTION will be given to you by a specially trained doctor or nurse. They will use one of the two methods:

- with a needle directly into a vein (IV), or
- Into an artery (intra-arterial perfusion)

.

Usual adult dose:

Your healthcare professional will decide on your dose based on your weight and height. Your dose may change based on how well you are responding to treatment and your blood test results.

Thromboembolic events

You should receive prophylaxis of venous thromboembolism for at least the first 5 months of treatment especially if you have additional thrombotic risk factors. Your doctor will decide what measures should be taken after careful assessment of your underlying risk factors.

If you experience any thromboembolic event, tell your doctor immediately as your treatment must be discontinued and a standard anticoagulation therapy started. Your doctor will decide if you should restart melphalan in combination with lenalidomide and prednisone or thalidomide and prednisone or dexamethasone once the thromboembolic events have been managed. You should continue anticoagulation therapy during the course of melphalan treatment.

Overdose:

If you think you, or a person you are caring for, have been given too much MELPHALAN FOR INJECTION contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss an appointment to receive a dose of MELPHALAN FOR INJECTION contact your healthcare professional as soon as possible.

What are possible side effects from using MELPHALAN FOR INJECTION?

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

Side effects may include:

- In women, periods may stop
- In men, sperm production may be reduced or stopped
- Nausea, vomiting, diarrhea
- Mouth ulcers or sores
- Hair loss
- Skin rash and/or itching
- Mild pain and/or irritation where MELPHALAN FOR INJECTION was injected
- Flushing, feelings of warmth and/or tingling
- Muscle pain, wasting, or scarring

MELPHALAN FOR INJECTION 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	
VERY COMMON			
Bone Marrow Suppression: signs and symptoms of infections (including fever, chills, sore throat, mouth ulcers), fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin lips and nail beds		✓	
COMMON			
Compartment Syndrome: pain, pale skin, numbness, tingling and weakness or paralysis in the leg or arm where MELPHALAN FOR INJECTION was injected		✓	
RARE			
Allergic Reaction: swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, rash, hives, fast heartbeat			✓
Liver Problems: yellowing of the whites of eyes or the skin, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Lung Problems (interstitial lung disease, pneumonitis): fatal and serious with suddenly worsening shortness of			✓

breath, wheezing, tiredness, possibly with a cough or fever, painful breathing			
Injection Site Reaction: severe muscle or nerve damage, pain, redness, inflammation, tenderness, ulcers or infection at the injection site that can lead to amputation			✓
NOT KNOWN			
Severe Muscle Breakdown (rhabdomyolysis): muscle weakness, fatigue, soreness, bruising, fever, passing little or no urine, tea-coloured urine			✓

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 (<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:

- MELPHALAN FOR INJECTION should be stored at controlled room temperature (15°-30°C).
- Protect from light.
- Keep out of reach and sight of children.

If you want more information about MELPHALAN FOR INJECTION:

- Talk to your healthcare professional
- You may want to read this leaflet again. **Please Do Not Throw It Away** until you have finished your medicine.
- 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.marcapharma.com, or by calling 1-855-627-2261

This leaflet was prepared by Marcan Pharmaceuticals Inc.

Last Revised: February 13, 2023