

# MELPHA<sup>®</sup> injection

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using MELPHA?

MELPHA contains the active ingredient Melphalan Hydrochloride. MELPHA is used to treat multiple myeloma, a cancer of the blood.

For more information, see Section [1. Why am I using MELPHA?](#) in the full CMI.

### 2. What should I know before I use MELPHA?

Do not use if you have ever had an allergic reaction to MELPHA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use MELPHA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MELPHA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use MELPHA?

- Your doctor will decide what dose and for how long you will be given MELPHA injection.

More instructions can be found in Section [4. How do I use MELPHA?](#) in the full CMI.

### 5. What should I know while using MELPHA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using MELPHA.</li><li>Do not have any vaccinations without your doctor's approval.</li><li>Tell your doctor if you become pregnant, are trying to become pregnant or trying to father a child.</li><li>If you are about to undergo surgery or an operation, tell your doctor or surgeon that you are being given MELPHA injection.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>You must not be given MELPHA injection if you have an allergy to:<ul style="list-style-type: none"><li>melphalan</li><li>any of the ingredients listed at the end of this leaflet.</li></ul></li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how MELPHA injection affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Consult your doctor if you are drinking alcohol while taking MELPHA</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep MELPHA injection in a cool, dry place where it stays below 25°C. protect from light</li><li>Keep this medicine where children cannot reach it, such as in a locked cupboard.</li><li>Return any unused or expired medicine to your pharmacist.</li></ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are being given MELPHA injection.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MELPHA<sup>®</sup> injection

Active ingredient(s): [Melphalan]

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MELPHA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MELPHA.**

**Where to find information in this leaflet:**

- [1. Why am I using MELPHA?](#)
- [2. What should I know before I use MELPHA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MELPHA?](#)
- [5. What should I know while using MELPHA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using MELPHA?

MELPHA contains the active ingredient **Melphalan Hydrochloride**. MELPHA injection contains melphalan Hydrochloride as the active ingredient. It belongs to a group of medicines called cytotoxics.

**MELPHA is used to used to treat multiple myeloma, a cancer of the blood.**

### 2. What should I know before I use MELPHA?

#### Warnings

**Do not use MELPHA if:**

- you are allergic to Melphalan Hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- [insert other relevant contraindications].

**Check with your doctor if you:**

- have any other medical conditions [list any notable ones for the medicine / medical condition here]
- take any medicines for any other condition

Tell your doctor as soon as possible if you do not feel well while you are being given MELPHA injection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not be given this medicine if you are trying to become pregnant or to father a child.

You must not be given MELPHA injection if you are pregnant or breast feeding unless you and your doctor have discussed the risks and benefits involved.

### Use in Children

- The safety and effectiveness in children has not been established.
- If you are not sure if you should be given this medicine, talk to your doctor.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by MELPHA injection or may affect how well it works.

**Some medicines may interfere with MELPHA and affect how it works.**

You may need to take different amounts of your medicine or you may need to take different medicines. These include:

- nalidixic acid
- cyclosporin
- cisplatin
- carmustine
- other cytotoxic drugs
- vaccinations with 'live' organism vaccines.

**Medicines that may increase the effect of MELPHA include:**

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

**Medicines that may reduce the effect of MELPHA include:**

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MELPHA.**

## 4. How do I use MELPHA?

### How much to take / use

- MELPHA for Injection is administered intravenously. The usual IV dose is 16 mg/m<sup>2</sup>. The drug is administered as a single infusion over 15 to 20 minutes. MELPHA is administered at 2-week intervals for four doses, then, after adequate recovery from toxicity, at 4-week intervals.
- Follow the instructions provided and use MELPHA until your doctor tells you to stop.

### When to take / use MELPHA

- MELPHA should be used to treat multiple myeloma, a cancer of the blood.
- Your doctor will decide what dose and for how long you will be given MELPHA injection.
- Your doctor may order regular blood tests while you are being given MELPHA injection in order to monitor your blood cell count and to change your dosage if necessary.
- MELPHA injection will be given to you under the supervision of a doctor.
- It is a sterile powder which is dissolved and then further diluted before intravenous infusion or 'drip' into a vein.

### How to administer MELPHA (relevant for devices)

MELPHA for Injection must be reconstituted AT ROOM TEMPERATURE by rapidly injecting 10 mL of the supplied diluent directly into the vial of lyophilised powder using a sterile needle (21 Gauge or higher Gauge size) and syringe. Immediately shake vial vigorously (for approximately 5 minutes) until a clear solution is obtained. This provides a 5-mg/mL solution of melphalan and has a pH of approximately 6.5. Rapid addition of the diluent, as a single quantity, followed by immediate vigorous shaking is important for proper dissolution.

### If you forget to use MELPHA

Your doctor will decide what dose and for how long you will be given MELPHA injection.

MELPHA until your doctor tells you to stop.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

- Your doctor will decide what dose and for how long you will be given MELPHA injection.
- Your doctor may order regular blood tests while you are being given MELPHA injection in order to monitor your blood cell count and to change your dosage if necessary.
- MELPHA injection will be given to you under the supervision of a doctor.

### If you use too much MELPHA

As MELPHA injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given MELPHA injection, tell your doctor immediately.

Symptoms of overdose may include severe nausea and vomiting, convulsions and stomach pain.

If you think that you have used too much MELPHA, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using MELPHA?

### Things you should do

**It is important that you visit your doctor regularly, so your doctor can check your progress and make sure your medicine is working.**

#### Call your doctor straight away if you:

- especially if you are about to be started on any new medicines or radiotherapy.
- Do not have any vaccinations without your doctor's approval.
- Tell your doctor if you become pregnant, are trying to become pregnant or trying to father a child.
- If you are about to undergo surgery or an operation, tell your doctor or surgeon that you are being given MELPHA injection.
- This medicine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.
- The following precautions should be taken to reduce your risk of infection or bleeding:
  - avoid people who have infections
  - Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.

- be careful when using a toothbrush, tooth pick or dental floss
- Check with your doctor before having dental work.
- Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums.
- be careful not to cut yourself when using sharp objects such as a razor or nail cutters
- avoid contact sports or other situations where you may bruise or get injured.

Remind any doctor, dentist or pharmacist you visit that you are using MELPHA.

### Things you should not do

- Do not stop using this medicine without consultation with your doctor.

### Bleeding and Infection

- This medicine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.
- The following precautions should be taken to reduce your risk of infection or bleeding:
  - avoid people who have infections
  - Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
  - be careful when using a toothbrush, tooth pick or dental floss
  - Check with your doctor before having dental work.
  - Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums.
  - be careful not to cut yourself when using sharp objects such as a razor or nail cutters
  - avoid contact sports or other situations where you may bruise or get injured.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how MELPHA affects you.**

MELPHA may cause dizziness in some people. Be careful driving or operating machinery until you know how MELPHA injection affects you.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may have different effect on different people. Consult your doctor if you are drinking alcohol while taking MELPHA.

### Looking after your medicine

- Keep MELPHA injection in a cool, dry place where it stays below 25°C. protect from light

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### When to discard your medicine (as relevant)

**Return any unused or expired medicine to your pharmacist.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>General side effect on body:</b></p> <ul style="list-style-type: none"> <li>• nausea and vomiting</li> <li>• diarrhoea</li> <li>• mild skin rash or itching</li> <li>• tingling sensation</li> <li>• persistent cough or breathlessness</li> <li>• pain or swelling at the injection site.</li> <li>• production of bone marrow cells may be reduced.</li> <li>• signs of fever</li> <li>• infection</li> <li>• unexpected bruising</li> <li>• bleeding or signs of blood in your urine.</li> <li>• hair loss</li> </ul> <p><b>Effect of gender:</b></p> <ul style="list-style-type: none"> <li>• in some women, periods may stop</li> <li>• in some men, sperm production may be reduced or stop.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>Your doctor will frequently test your blood count, but you should tell him at once if you notice any signs of fever, infection, unexpected bruising, bleeding or signs of blood in your urine.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Bleeding-related:</b></p> <ul style="list-style-type: none"><li>bruising or bleeding more easily than normal, nose bleeds</li></ul> <p><b>Other body related:</b></p> <ul style="list-style-type: none"><li>wheezing, swelling of the lips or mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting</li><li>frequent infections such as fever, sore throat or mouth ulcers</li><li>unusual tiredness, looking pale, feeling weaker, dizzy or more tired than usual</li><li>jaundice, a yellowing of the whites of the eyes or skin</li><li>problems with your eyesight</li><li>unusually fast heartbeat.</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What MELPHA contains

<b>Active ingredient (main ingredient)</b>	Melphalan Hydrochloride
<b>Other ingredients (inactive ingredients)</b>	Each vial of sterile powder for injection contains 50 mg melphalan Hydrochloride and povidone. Each vial of sterile diluent contains sodium citrate Dihydrate, propylene glycol, ethanol and water for injections.

Potential allergens	NA
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**Do not take this medicine if you are allergic to any of these ingredients.**

### What MELPHA looks like

MELPHA injection is supplied in a carton containing:

- one clear glass vial containing sterile, white or off-white powder for injection
- one 10 mL clear glass vial containing a sterile, clear, colourless solution of diluent.

The diluent is used to dissolve the powder. (Aust R 287038).

### Who distributes MELPHA

#### Australia

**Sponsor: Emcure Pharmaceuticals Pty Ltd.**

**Distributed by: Arrotex Pharmaceuticals Pty Ltd**

15-17 Chapel Street

Cremorne VIC 3121

[patient.safety@arrotex.com.au](mailto:patient.safety@arrotex.com.au)

#### New Zealand

**Sponsor & Distributor:**

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This leaflet was prepared in July 2025.