

MELPHA® injection

Melphalan

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MELPHA injection. It does not contain all of the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you MELPHA injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet while being treated.

You may need to read it again.

What MELPHA injection is used for

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

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

It is thought to work by stopping cancer cells from growing and multiplying.

This medicine may be used in combination with other medicines to treat cancer.

Ask your doctor if you have any questions about why MELPHA injection has been prescribed for you.

Your doctor may have prescribed it for another purpose.

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

There is no evidence that it is addictive.

Before you are given it

When you must not be given it

You must not be given MELPHA injection if you have an allergy to:

- melphalan
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

You must not be given MELPHA injection if you have an infection or a high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

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

MELPHA injection may harm eggs and sperm. Reliable contraceptive methods must be taken to avoid pregnancy whilst you or your partner is being treated with this medicine and for at least 12 weeks after either partner stops being given it.

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.

You must not be given this medicine after the expiry date has passed or if the packaging is torn or shows signs of tampering.

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.

Before you are given it

Tell your doctor if you are allergic to any other medicines or any foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following conditions:

- you have recently received or are receiving radiotherapy or chemotherapy
- you have recently been vaccinated or are planning to be vaccinated
- kidney disease
- blood disorders
- you have received MELPHA treatment previously.

If you have not told your doctor about any of the above, tell them before you are given MELPHA injection.

Taking other medicines

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

Some medicines may be affected by MELPHA injection or may affect

how well 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.

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

How it is given

How much is given

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.

How it is given

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.

If you take too much (overdose)

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.

While you are receiving it

Things you must do

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

Tell any other doctor, dentist or pharmacist that you are being given MELPHA injection, especially if you are about to be started on any new medicines or radiotherapy.

Do not have any vaccinations without your doctor's approval.

MELPHA may lower your body's resistance and there is a chance you might get the infection the vaccination is meant to prevent.

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.

Things to be careful of

Be careful driving or operating machinery until you know how MELPHA injection affects you.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The following side-effects have been reported with melphalan injection:

- production of bone marrow cells may be reduced.
- **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.**
- hair loss
- in some women, periods may stop
- in some men, sperm production may be reduced or stop.

Tell your doctor if you notice any of the following and they worry you:

- nausea and vomiting
- diarrhoea
- mild skin rash or itching

- tingling sensation
- persistent cough or breathlessness
- pain or swelling at the injection site.

Tell your doctor immediately if you notice any of the following:

- wheezing, swelling of the lips or mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting
- frequent infections such as fever, sore throat or mouth ulcers
- bruising or bleeding more easily than normal, nose bleeds
- unusual tiredness, looking pale, feeling weaker, dizzy or more tired than usual
- jaundice, a yellowing of the whites of the eyes or skin
- problems with your eyesight
- unusually fast heart beat.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of side effects.

You may not experience any of them.

After using it

Things to be aware of

Because of the way this medicine works there is a chance it might cause other unwanted effects that may not occur until months or years after the medicine is used. These delayed effects may include certain types of cancer, such as leukaemia.

Discuss these possible effects with your doctor.

Storage

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

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Return any unused or expired medicine to your pharmacist.

Product description

What it 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.

Ingredients

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.

Sponsor

Emcure Pharmaceuticals Pty Ltd.

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