



Package Leaflet: Information for the User
Melphalan 2mg tablets
melphalan

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions about your illness or your medicine, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.



- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What Melphalan is and what it is used for
2. Before you take Melphalan
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1. What Melphalan is and what it is used for

Melphalan tablets contain a medicine called melphalan. This belongs to a group of medicines called cytotoxics (also called chemotherapy). Melphalan is used to treat cancer. It works by reducing the number of abnormal cells your body makes.

Melphalan is used for:

- Multiple myeloma – a type of cancer that develops from cells in the bone marrow called plasma cells. Plasma cells help to fight infection and disease by producing antibodies
 - Advanced cancer of the ovaries
 - Advanced breast cancer
 - Polycythaemia vera – a disease which increases the number of red cells in your blood. This makes the blood thicken and causes blood clots. This leads to headaches, dizziness and shortness of breath
- Ask your doctor if you would like more explanation about these diseases.

2. Before you take Melphalan

Do not take Melphalan if:

- You are allergic (hypersensitive) to melphalan or any of the other ingredients of Melphalan tablets (See section 6: Further information)
- Do not take if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Melphalan.
- Take special care with Melphalan
- Before you take Melphalan, tell your doctor or pharmacist if:
- you have had radiotherapy or

chemotherapy, now or recently

- you have a kidney problem.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking 2 Melphalan.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular, you must tell your doctor if you are taking any of the following:

- other cytotoxic drugs (chemotherapy)
- nalidixic acid (an antibiotic used to treat urinary tract infections)
- ciclosporin (used to prevent rejection of organs or tissues following a transplant or to treat certain skin conditions like psoriasis and eczema or to treat rheumatoid arthritis).

Having vaccines while you are taking Melphalan

If you are going to have a vaccination speak to your doctor or nurse before you have it. This is because some vaccines (like polio, measles, mumps and rubella) may give you an infection if you have them whilst you are taking Melphalan.

Pregnancy and breast-feeding

Do not take Melphalan if you are planning to have a baby. This applies to both men and women. Melphalan may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy

whilst you or your partner is taking these tablets. Ask your doctor for advice.

If you are already pregnant, it is important to talk to your doctor before taking Melphalan.

Do not breast-feed while taking Melphalan. Ask your doctor or midwife for advice.

3. How to take Melphalan

Melphalan should only be given to you by a specialist doctor who is experienced in treating blood problems or cancer.

Always take Melphalan exactly as your doctor has told you. It is important to take your medicine at the right times. The label on your pack will tell you how many tablets to take and how often to take them. If the label doesn't say or if you are not sure, ask your doctor, nurse or pharmacist.

- Swallow your tablets whole with a glass of water.
- Do not break, crush or chew the tablets.

The dose of Melphalan depends on your blood problem or cancer (see section 1).

- Your doctor may also change your dose during your treatment, depending on your needs.
- The dose can sometimes be changed if you are elderly or have a kidney problem.
- When you take Melphalan, your doctor will take regular blood tests. This is to check the number of cells in your blood. Your doctor may sometimes change your dose as a result.

Multiple myeloma

- The usual dose is 0.15 mg per kilogram of your body weight each day for 4 days. This is repeated every 6 weeks.

Advanced ovarian adenocarcinoma

- The usual dose is 0.2 mg per kilogram of your body weight each day for 5 days. This is repeated every 4 to 8 weeks.

Advanced breast carcinoma

- The usual dose is 0.15 mg per kilogram of your body weight each day for 5 days. This is repeated every 6 weeks.

Polycythaemia vera

- Initially 6 to 10 mg each day for 5 to 7 days. The dose will then be reduced to 2 to 4 mg each day.
- If you take more Melphalan than you should

If you take more Melphalan than you should, tell your doctor immediately or go to a hospital straight

away. Take the medicine pack with you.

If you forget to take Melphalan

Tell your doctor. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Melphalan can cause side effects, although not everybody gets them.

If you get any of the following, talk to your specialist doctor or go to hospital straight away:

- allergic reaction, the signs may include:
 - a rash, lumps or hives on the skin
 - swollen face, eyelids or lips

- sudden wheeziness and tightness of the chest

- collapse (due to cardiac arrest)

- any signs of fever or infection (sore throat, sore mouth or urinary problems)

- any unexpected bruising or bleeding or feeling extremely tired, dizzy or breathless, as this could mean that too few blood cells of a particular type are being produced
- if you suddenly feel unwell (even with a normal temperature).

Talk to your doctor if you have any of the following side effects which may also happen with this medicine:

Very common (affects more than 1 in 10 people)

- a drop in the number of blood cells and platelets

- feeling sick (nausea), being sick (vomiting) and diarrhoea
- mouth ulcers - with high doses of Melphalan

- hair loss - with high doses of Melphalan

Common (affects less than 1 in 10 people)

- hair loss - with usual doses of Melphalan
 - high levels of a chemical called urea in your blood – in people with kidney problems who are being treated for myeloma
- Rare (affects less than 1 in 1,000 people)

- an illness where you have a low number of red blood cells as they are being destroyed prematurely – this can make you feel very tired, breathless and dizzy and can give you headaches or make your skin or eyes yellow

- lung problems which may make you cough or wheeze and make it difficult to breathe
 - liver problems which may show up in your blood tests or cause jaundice (yellowing of the whites of eyes and skin)
 - mouth ulcers – with normal doses of Melphalan
 - skin rashes or itching skin
- The following side effects also happen with Melphalan:

- leukaemia – cancer of the blood
 - in women: your periods stopping
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Melphalan

- Keep out of the reach and sight of children.
- Do not use Melphalan after the expiry date, which is stated on the pack after 'Exp'.
- Store in a refrigerator between 2 and 8°C.

- If your doctor tells you to stop taking the tablets, it is important to return any which are left over to your pharmacist, who will destroy them according to disposal of dangerous substance guidelines. Only keep the tablets if your doctor tells you to.

6. Further information

What Melphalan contains

The active ingredient is melphalan. Each Melphalan tablet contains 2 mg of melphalan. The other ingredients are microcrystalline cellulose,

crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide and macrogol.

What Melphalan looks like and contents of the pack
Melphalan tablets are white to off-white film-coated, round, biconvex tablets engraved with 'TAJ EH3' on one side and 'A' on the other. Your Melphalan tablets are in bottles of 25 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:



Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
Mumbai, India
at SURVEY NO.188/1 TO
189/1,190/1 TO 4, ATHIYAWAD,
DABHEL, DAMAN- 396210 (INDIA)

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TAJ PHARMA