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PACKAGE LEAFLET

Package Leaflet: Information for the user

Melphalan 2 mg tablets melphalan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Melphalan is and what it is used for
2. What you need to know before you take Melphalan
3. How to take Melphalan
4. Possible side effects
5. How to store Melphalan
6. Contents of the pack and other information

1. What Melphalan is and what it is used for

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

Melphalan tablet 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 type of blood cancer where the number of red cells in your blood increases due to uncontrolled red blood cell production in your body. This makes the blood thicken and causes blood clots, and may result in headaches, dizziness and shortness of breath

Ask your doctor if you would like more explanation about these diseases.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Melphalan

Do not take Melphalan if:

- You are allergic to melphalan or any of the other ingredients of this medicine (listed in section 6).
- You are breastfeeding.

If you are not sure, talk to your doctor or pharmacist before taking Melphalan.

Warnings and precautions

Before you take Melphalan, tell your doctor or nurse if:

- you have had radiotherapy or chemotherapy, now or recently,
- you have a kidney problem, you are going to have a vaccination or were recently vaccinated. 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.
- you are using combined oral contraception (the pill). This is because of the increased risk of venous thromboembolism in patients with multiple myeloma. You should switch to ovulation inhibitory progesterone-only pills (i.e., desogestrel). The risk of venous thromboembolism continues for 4–6 weeks after discontinuing combined oral contraception.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before taking Melphalan.

Melphalan could increase the risk of developing other types of cancer (eg secondary solid tumours) in a small number of patients, particularly when used in combination with lenalidomide, thalidomide and prednisone. Your doctor should carefully evaluate the benefits and risks when you are prescribed Melphalan.

Other medicines and Melphalan

Please tell your doctor if you are taking, have recently taken or might take 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:

- vaccines which contain live organisms (see Warnings and precautions)
- 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).
- in children, busulfan (anti-cancer medicine)

Pregnancy, breast-feeding and fertility

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take Melphalan if you are planning to have a baby. This applies to both men and women. Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner is taking these tablets.

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 for advice.

Fertility

Melphalan can affect ovaries or sperm, which may cause infertility (inability to have a baby). In woman, menstruation can stop (amenorrhoea) and in men, a complete lack of sperm can be observed (azoospermia). Due to the possibility of the lack of sperm as a result of Melphalan treatment it is advised for men to have a consultation on sperm preservation before treatment. It is recommended that men who are receiving treatment with Melphalan not father a child during treatment and up to 6 months afterwards.

Driving and using machines

Effects on the ability to drive and operate machinery in patients taking this medicine have not been studied.

3. How to take Melphalan

Melphalan should only be given to you by a specialist doctor who is experienced in treating 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 the type of 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 an older person 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.

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.

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.

If you stop taking Melphalan

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine 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

Not known (frequency cannot be estimated from the available data)

- leukaemia - cancer of the blood
- in women: your periods stopping (amenorrhoea)
- in men: absence of sperms in the semen (azoospermia)
- deep vein thrombosis (formation of a blood clot called thrombus within a deep vein, predominantly in the legs) and pulmonary embolism (a blockage of the lung's main artery or its branches by a blood clot that breaks off and travels to the lung)

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.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Melphalan

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the pack after 'Exp'. The expiry date refers to the last day of that month.
- 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.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Melphalan contains

The active substance 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 'GX EH3' on one side and 'A' on the other. Your Melphalan tablets are in bottles of 25 and 50 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:
Aspen Pharma Trading Limited
3016 Lake Drive,
Citywest Business Campus,
Dublin 24, Ireland
Service-Tel: 0800 008 7392 (+ 44 1748 828 391)
Manufacturer: EXCELLA GmbH, 90537 Feucht, Germany

Medical Information Enquiries

For any Medical Information enquiries about this product, please contact: 24 Hour Helpline +441748 823 391 (free phone UK only 0800 0087 392).

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: **0800 198 5000 (UK only)**.

Please be ready to give the following information:

Product name: Melphalan 2 mg tablets

Reference number: PL 39699/ 0043

This is a service provided by the Royal National Institute of Blind People.

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