

1.3.2 PATIENT INFORMATION LEAFLET



SCHEDULING STATUS: **S4 / S3**

MELPISPAL 50 mg powder for injection

MELPISPAL SD solvent for injection

Melphalan

Sugar Free

Read all of this leaflet carefully before you are given MELPISPAL 50

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What MELPISPAL 50 is and what it is used for
2. What you need to know before you use MELPISPAL 50
3. How to use MELPISPAL 50
4. Possible side effects
5. How to store MELPISPAL 50
6. Contents of the pack and other information

1. What MELPISPAL 50 is and what it is used for

MELPISPAL 50 injection contains a medicine called melphalan. This belongs to a group of medicines called cytotoxics (also called chemotherapy). MELPISPAL 50 is used to treat cancer. It works by reducing the number of abnormal cells your body makes.

MELPISPAL 50 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



- Childhood neuroblastoma - cancer of the nervous system
- Malignant melanoma – skin cancer
- Soft tissue sarcoma – cancer of the muscle, fat, fibrous tissue, blood vessels, or other supporting tissue of the body

2. What you need to know before you use MELPISPAL 50

MELPISPAL 50 should not be administered to you:

- If you are allergic (hypersensitive) to melphalan or any of the other ingredients of MELPISPAL 50 injection (listed in section 6).
- If you are pregnant or breastfeeding.
- if you are planning or recently been vaccinated with live vaccine.

Do not have MELPISPAL 50 if the above applies to you. If you are not sure, talk to your doctor or nurse before having MELPISPAL 50.

Warnings and precautions

- Before treatment with MELPISPAL 50, tell your doctor if any of the following apply to you:
 - 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 being treated with MELPISPAL 50.
 - you have a blood clot in your leg (thrombosis), lung (pulmonary embolism) or any other part of your body or have ever had it.
 - you have a condition that gives you an increased chance of getting a blood clot in your arteries.



- men who are receiving MELPISPAL 50 should not father a child during treatment and up to 3 months afterwards.

MELPISPAL 50 contains ethanol (alcohol)

This medicine contains 5,2 % ethanol (alcohol). Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breastfeeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

MELPISPAL 50 contains propylene glycol

May cause alcohol-like symptoms.

Other medicines and MELPISPAL 50

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

In particular, tell your doctor or nurse if you are taking any of the following

- other cytotoxic medicines (chemotherapy)
- nalidixic acid (an antibiotic used to treat urinary tract infections)
- ciclosporin (used to prevent rejection following a transplant, to treat certain skin conditions like psoriasis and eczema or to treat rheumatoid arthritis)
- vaccines which contain live organisms (see Warnings and precautions)
- in children, busulfan (used to treat certain type of cancer).

Please tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicines, including vaccinations and medicines obtained without a prescription.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

Do not have MELPISPAL 50 if you are planning to have a baby. This applies to both men and women. MELPISPAL 50 may harm your sperm or eggs.

Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are having this injection. Ask your doctor for advice.

If you are already pregnant, it is important to talk to your doctor before having MELPISPAL 50.

Do not breast-feed while having MELPISPAL 50.

Driving and using machines

MELPISPAL 50 has no or negligible influence on the ability to drive and use machines.

It is not always possible to predict to what extent MELPISPAL 50 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MELPISPAL 50 affects them.

3. How MELPISPAL 50 powder for injection is given

You will not be expected to give yourself MELPISPAL 50. It will be given to you by a person who is qualified to do so.

MELPISPAL 50 will only be given to you by doctors or nurses experienced in giving chemotherapy.

MELPISPAL 50 can be given

- as an infusion (drip) into your vein
- into an artery, administered to a certain body part (perfusion).



Your doctor will decide how much MELPISPAL 50 you will be given. The amount of MELPISPAL 50 depends on

- your body weight or body surface area (a specific measurement taking into account your weight and your size)
- other drugs you are having
- your disease
- your age
- whether or not you have kidney problems.

When you are given MELPISPAL 50, your doctor will take regular blood tests. This is to check the number of cells in your blood. Your doctor may change your dose as a result of these tests.

Risk of blood clots (thromboembolic events):

Your doctor will decide if you should receive a preventive treatment for blood clots in the veins. This applies during the first 5 months of treatment, or if you have an increased risk for developing a blood clot in the veins.

Use in children

MELPISPAL 50 is only rarely used in children. Dosing guidelines for children are not available.

Use in elderly

There are no specific dosage adjustments for the elderly.

Use in patients with impaired renal function



If you have a kidney problem, your doctor will usually give you a lower dose than other adults.

If you are given more MELPISPAL 50 than you should

Your doctor will give you MELPISPAL 50 so it is unlikely that you will receive too much. If you think you have been given too much or have missed a dose, tell your doctor or nurse.

If you forget to use MELPISPAL 50

Your doctor will give you MELPISPAL 50 so it is unlikely that you will miss a dose of this medicine.

4. Possible side effects

MELPISPAL 50 can have side effects.

Not all side effects reported for MELPISPAL 50 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving MELPISPAL 50, please consult your healthcare provider for advice.

If any of the following happens, stop taking MELPISPAL 50 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- sudden wheeziness, difficulty breathing, chest pain or chest tightness,
- swelling of the hands, feet, ankles, eyelids, face, lips, mouth or tongue/throat, which may cause difficulty in swallowing or breathing,
- lumpy skin rash, itching or “hives” anywhere on the body.

These are all very serious side effects. If you have them, you may have had a serious reaction to MELPISPAL 50. You may need urgent medical attention or hospitalisation.



Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- break down of skeletal muscles (rhabdomyolysis) leading to tenderness, swelling and weakness of affected muscles,
- blood clot in a deep vein or arteries, symptoms may include but are not limited to swelling in your foot, ankle, or leg, usually on one side. Cramping pain in your affected leg that usually begins in your calf.

Severe, unexplained pain in your foot and ankle. An area of skin that feels warmer than the skin on the surrounding area,

- blood clots in the lungs. Symptoms may include but are not limited to anxiety, clammy or bluish skin, chest pain that may extend into your arm, jaw, neck, and shoulder, fainting, irregular heartbeat and light headedness, effects on the blood may occur. Your doctor will do regular blood tests, but you should tell him/her at once if you notice any signs of fever or infection, or any unexpected bruising or bleeding,
- haemolytic anaemia. This results from the destruction of red blood cells. As a result, you may feel tired and dizzy, get headaches, look pale with a yellowing of the skin and/or eyes,
- any signs of jaundice (yellowing of the whites of the eyes or the skin) as this may be due to hepatitis (inflammation/infection of the liver). If you have any blood tests to check how your liver is working, MELPISPAL 50 may affect the results,
- your muscles are achy, stiff or weak, your urine is darker than usual or brown or red in colour,
- that you are gradually becoming more breathless than usual,
- a drop in the number of blood cells and platelets,
- MELPISPAL 50 has been reported to cause cancers in some patients who have been treated with MELPISPAL 50.

These are all serious side effects. You may need urgent medical attention.



Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling sick (nausea), being sick (vomiting) and diarrhoea,
- hair loss,
- a tingling or warm feeling where MELPISPAL 50 was injected,
- a muscle problem which can cause pain, tightness, tingling, burning or numbness, called compartment syndrome.

Less frequent side effects:

- sore mouth.

Side effects with an unknown frequency:

- in women, periods may stop,
- in men, sperm production may be reduced or stopped.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MELPISPAL 50

5. How to store MELPISPAL 50



Store all medicines out of reach of children.

Store at or below 30 °C

Store in the original package to protect from light.

Contents of the pack and other information

What MELPISPAL 50 contains

- The active substance is Melphalan
- The other ingredients are:
- Povidone K12, water for injection

What MELPISPAL 50 looks like and contents of the pack

MELPISPAL 50 is a white to off white coloured lyophilized powder or cake

MELPISPAL SD is a clear colourless solution

MELPISPAL 50:

50 mg freeze-dried powder is packed in a 15 ml clear 20 mm collar vials (flat bottom) with 20 mm lyostoppers bromobutyl (single slotted) and sealed with 20 mm easy to open C/L ALU seals with matte finish plastic grey.

MELPISPAL SD:

Solvent is packed in 15 mL clear 20 mm collar vials (flat bottom) with 20 mm serum laminated chlorobutyl rubber stoppers and sealed with 20 mm easy to open C/L ALU seals with matte finish plastic white.

A vial of MELPISPAL 50 is packed together with a vial of MELPISPAL SD into a cardboard box with a leaflet.

Holder of Certificate of Registration

Ruby Pharmaceuticals (Pty) Ltd.

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A handwritten signature in black ink, consisting of a stylized 'R' followed by a flourish.