1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4 ALKERAN 50

S3 ALKERAN SD

ALKERAN 50 powder for injection

Melphalan (anhydrous) hydrochloride

Sugar free

ALKERAN SD solution for injection

Ethanol, propylene glycol, water for injection

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ALKERAN 50 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ALKERAN 50 is and what it is used for
2. What you need to know before you receive ALKERAN 50
3. How to receive ALKERAN 50
4. Possible side effects

5. How to store ALKERAN 50
6. Contents of the pack and other information

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

ALKERAN 50 contains the active substance melphalan (anhydrous) hydrochloride.

ALKERAN 50 belongs to a group of medicines called cytotoxics. It is used for the treatment of certain forms of cancer:

- Multiple myeloma (cancer in the bone marrow).
- Ovarian cancer.
- Neuroblastoma (cancer in the adrenal glands) in childhood.
- Malignant melanoma – skin cancer.
- Soft tissue sarcoma.

2. What you need to know before you receive ALKERAN 50

ALKERAN 50 should not be administered to you:

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

Warnings and precautions

Tell your doctor or healthcare provider before being given ALKERAN 50:

- if you have a kidney problem.
- if you have had radiotherapy or chemotherapy, now or recently.
- if you are taking combined oral contraception.

- if you are planning to have a baby, ALKERAN 50 may harm the sperm, eggs and/or baby, so highly effective contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are receiving these injections; ask your doctor for advice.
- if you are taking lenalidomide and prednisone or thalidomide and prednisone or dexamethasone.
- if you are an elderly patient.

Your doctor will monitor:

- Your blood counts.
- You before, during and after treatment with ALKERAN 50 to ensure the early detection of cancer and initiate treatment if necessary.

Other medicines and ALKERAN 50

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

Tell your doctor if you are taking any of the following medicines:

- Other cytotoxic medicines (chemotherapy).
- Nalidixic acid (an antibiotic used to treat urinary tract infections).
- Live organism vaccines.
- 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).

Pregnancy, breastfeeding and fertility

You should not receive ALKERAN 50 if you are pregnant or breastfeeding your baby. 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 ALKERAN 50.

Treatment with ALKERAN 50 is not recommended during pregnancy because it may cause permanent damage to a foetus.

Highly effective contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are receiving ALKERAN 50.

Fertility

Melphalan, as in ALKERAN 50, can affect ovaries or sperm, which may cause infertility (inability to have a baby). In women, menstruation can stop (amenorrhoea) and in men, a complete lack of sperm can be observed (azoospermia) as a result of ALKERAN 50 treatment. Therefore, men are advised to have a consultation on sperm preservation before treatment.

Driving and using machines

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

It is not always possible to predict to what extent ALKERAN 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 ALKERAN 50 affects them.

3. How to receive ALKERAN 50

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

ALKERAN 50 will be prescribed and used only by doctors trained and experienced in the management of cancer. Great care is required in the preparation and handling of ALKERAN 50. If you are present when it is being prepared, do not be surprised to see the clinician wearing

protective clothing including special gloves, a surgical facemask, protective goggles or glasses, and a disposable apron.

Your doctor will decide how much ALKERAN 50 you will be given. Your doctor will vary your dose depending on your weight and the type of cancer you may have, as well as your response to ALKERAN 50.

If you have the impression that the effect of ALKERAN 50 is too strong or too weak, tell your doctor or pharmacist.

If you receive more ALKERAN 50 than you should

Since a healthcare professional will administer ALKERAN 50, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
You may feel nausea and the urge to vomit. Diarrhoea sometimes also occurs. You may also feel weak and tired. Tell your doctor if you are feeling unwell.

If you forget to receive ALKERAN 50

Since a healthcare provider will administer ALKERAN 50, it is unlikely that a dose will be missed.

4. Possible side effects

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

If any of the following happens, stop taking ALKERAN 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 ALKERAN 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, ALKERAN 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,
- ALKERAN 50 has been reported to cause cancers in some patients who have been treated with ALKERAN 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 ALKERAN 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 side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of ALKERAN 50.

5. How to store ALKERAN 50

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ALKERAN 50 contains

ALKERAN 50:

The active substance in ALKERAN 50 is melphalan (anhydrous) hydrochloride 50 mg.

The other ingredient is povidine.

ALKERAN SD:

ALKERAN SD solvent contains ethanol, propylene glycol and water for injection.

What ALKERAN 50 looks like and contents of the pack

ALKERAN 50:

Powder for injection.

White to off-white freeze-dried powder When dissolved in 10 ml of ALKERAN SD is practically free from visible particles.

ALKERAN SD:

Solution for injection.

Clear colourless solution, practically free from visible particles.

ALKERAN 50:

50 mg freeze-dried powder is packed in a clear, neutral glass vial of nominal capacity of 17 ml, and closed with a bromobutyl rubber stopper and aluminium collar with a plastic flip-top cover.

ALKERAN SD:

10 ml is packed in a clear, neutral glass vial and closed with a chlorobutyl stopper and an aluminium collar with a plastic flip-top cover.

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

Holder of Certificate of Registration

PHARMACARE LIMITED

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Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

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