

ALKERAN™ Injection

Melphalan Injection 50mg.

Consumer

Medicine

Information

What is in this leaflet

This document answers some common questions about ALKERAN, a medicine used in the treatment of certain forms of cancer. 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 prescribing ALKERAN against the benefits he or she expects it will have.

If you have any concerns about the use of this medicine ask your doctor or pharmacist.

What is ALKERAN used for?

ALKERAN contains the active ingredient melphalan.

ALKERAN is a medicine used in the treatment of certain forms of cancer.

ALKERAN belongs to a group of medicines called alkylating agents, which work by stopping the growth of cancer cells and thus inhibiting the spread of the cancer. Cancer medicines are also known as cytotoxic agents.

A complication of tumours is known as malignancy. Malignancy may lead to pain, wasting, nausea, numbness or weakness of the arms and legs, loss of appetite, seizures, joint aches as well as problems with your internal organs such as your lungs, kidneys, liver etc.

ALKERAN is used:

- In the treatment of localised malignant melanoma of the hands and feet.
- In early malignant cases it is

usually prescribed for use as a supportive measure after surgery.

- In advanced but localised cases it is usually prescribed to help reduce pain and discomfort.

A melanoma is a tumour arising from the pigment-producing cells in the skin.

‘Localised’ means the tumour has probably not spread to other parts of the body.

- In the treatment of localised soft tissue (muscle and flesh) sarcoma of the hands and feet. It is used in the management of all stages of this sarcoma. It is sometimes given with another cytotoxic called actinomycin D.

A sarcoma is a malignant tumour that occurs in bones and soft tissue.

It is also used in:

- Multiple myeloma (cancer in the bone marrow).
- Advanced ovarian cancer.
- Advanced neuroblastoma (cancer in the adrenal glands) in childhood.

ALKERAN is only available through a doctor’s prescription.

How ALKERAN is used

ALKERAN is usually given intravenously (injected slowly in a diluted form) at various doses and intervals, alone or with one or more other drugs. It may also be used in conjunction with surgery and radiotherapy.

Before you are given ALKERAN

When ALKERAN should NOT be used

Tell your doctor if:

- You have previously had an allergic reaction to melphalan or any of ALKERAN’s other ingredients listed at the end of this document.
- You are pregnant, trying to become pregnant, breastfeeding or trying to father a child.

ALKERAN may affect the sperm, eggs and/or unborn baby, especially in the first trimester (first 3 months) of pregnancy. Reliable contraceptive precautions MUST be taken to avoid pregnancy whilst you or your partner are taking these tablets. Your doctor will weigh up the expected benefits of ALKERAN to you against the possible risk to your unborn baby.

It is recommended that you avoid getting pregnant while on ALKERAN.

- You have been vaccinated, or plan to be vaccinated with a live vaccine.
- You are allergic to any medicines, foods, dyes or preservatives.
- You are taking any other medicines that you have been prescribed, or have bought from a pharmacy, supermarket or health food shop.
- If you have recently undergone radiotherapy or chemotherapy.
- If you have renal impairment (reduced kidney

function).

Your doctor may do some blood tests to check that your kidneys are working properly and that your blood count is normal.

Taking other medicines

Some medicines may affect the way others work.

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

If you are taking any of the following medicines, tell your doctor:

- Nalidixic acid (Negram™), a medicine used to treat bacterial infections
- Cyclosporin (Neoral™, Sandimmun™) medicines used for the prevention of transplant rejection

Taking ALKERAN

Like all similar substances, ALKERAN 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. If you are present when it is being prepared or used 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 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.

While taking ALKERAN

Things you should do

- Tell your doctor if you feel that ALKERAN is not helping your condition.
- Tell your doctor if you become pregnant, planning to become pregnant or are breastfeeding.
- Drink plenty of water to make sure that your kidneys are working properly and your body is sufficiently hydrated.
- As with all medicines used to treat cancer, you should use reliable contraception when taking MYLERAN, whether you are male or female.

Things you should not do

- Do not breastfeed unless your doctor tells you that it is all right to do so
- Do not take any other medications whether they require a prescription or not without first consulting with your doctor or pharmacist.

If too much ALKERAN is given (overdose)

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.

Side-Effects

Tell your doctor or pharmacist as soon as possible if you have any problems while using ALKERAN, even if you think the problems are NOT connected with the medicine or are NOT LISTED in this document.

Like other medicines,

ALKERAN can cause some side-effects. If they occur they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Common side-effects include:

- Bone marrow depression leading to reduced blood counts and a tendency to bruise easily. The bruises can be obvious, large and dark. As a result you may feel tired and dizzy, get headaches, look pale.
- Diarrhoea, vomiting and inflammation of the mouth (mouth ulcers).
- Allergic reactions such as itchiness and skin rashes, hives and swelling of the face, shortness of breath. Cardiac arrest is sometimes (but rarely) associated with such reactions.
- Hair loss (uncommon at normal doses).
- A sensation of warmth and/or tingling.
- 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.

If you think you are having an allergic (hypersensitivity) reaction to ALKERAN TELL YOUR DOCTOR IMMEDIATELY. Symptoms include:

- Severe skin rash, itching or hives.
- Swelling of the face, lips, mouth or throat.
- Difficulty breathing and swallowing.
- Fever
- Low blood pressure (feeling dizzy and weak)

If any of these side-effects persist, or are troublesome, tell your doctor.

Ask your doctor or pharmacist to answer any questions you may have.

In women, ALKERAN may cause the menstrual cycle (period) to change. Tell your doctor if you notice anything different.

ALKERAN may affect both male and female fertility. Your doctor will probably discuss this with you.

Tell your doctor if you notice any changes.

This is not a complete list of all possible side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Product Description

ALKERAN Injection is dispensed as a unit pack comprising 50mg of Melphalan in the form of a freeze-dried powder and a 10mL vial of a liquid into which the powder is dissolved immediately before use.

Ingredients

ALKERAN Injection (freeze-dried), Melphalan, Hydrochloric Acid, Povidone K12, Solvent-diluent for ALKERAN Injection, Sodium Citrate, Propylene Glycol, Ethanol (96 per cent), Water for Injection.

Manufacturer

ALKERAN is supplied by:

Glaxo Wellcome New Zealand Limited
Quay Tower
Cnr Albert and Customs St
Private Bag 106600
Downtown Auckland
New Zealand

Ph: (09) 367 2900

Fax (09) 367 2910

Further information

Your doctor or clinician is the best person to give you advice on the use of ALKERAN and its use in the treatment of a particular condition. You may also be able to find general information about your illness and its treatment from other sources including books in public libraries.

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Version 1.0

Prepared November 2004.