

Alkeran(R) Injection

melfalan

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Alkeran Injection. 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 giving you Alkeran against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet while being treated.

You may need to read it again.

What Alkeran Injection is used for

Alkeran belongs to a group of medicines called cytotoxics. You may also hear of these being called chemotherapy medicines.

Alkeran is used to treat multiple myeloma, a cancer of the blood.

Alkeran is thought to work by stopping cancer cells from growing and multiplying.

Your doctor may have prescribed Alkeran for another reason.

Ask your doctor if you have any questions about why Alkeran has been prescribed for you.

Alkeran may be used in combination with other medicine to treat cancer.

Alkeran is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given Alkeran

Do not have it if:

- * **You have ever had an allergic reaction to melfalan or any of the ingredients listed at the end of this leaflet.**
- * **You have an infection or a high temperature.**

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

- * You are pregnant, trying to become pregnant, or likely to father a child unless your doctor says you should.

Alkeran may harm the sperm, eggs and/or baby so reliable contraceptive methods **MUST** be taken to avoid pregnancy whilst you or your partner are being given Alkeran.

Alkeran may cause birth defects if used any time during pregnancy, or if either the male or female has used it at the time of conception.

It is recommended that you use a reliable form of birth control while you are being treated with Alkeran and for at least 12 weeks after you stop using it.

Your doctor will discuss the risks and benefits of using Alkeran if you are pregnant.

- * **You are breast feeding.**

Alkeran may pass into the breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Tell your doctor if:

- * You have recently received, or are receiving, radiotherapy.
- * You have recently been vaccinated, or are planning to be vaccinated.
- * You are taking, or likely to be taking corticosteroids, cyclosporin, cisplatin, carmustine, nalidixic acid or other cytotoxic drugs.
- * You suffer from kidney disease. This is because your doctor may need to adjust the amount of Alkeran given to you.
- * You suffer from a blood disorder.
- * You are planning, or likely to have surgery.
- * You are allergic to foods, dyes, preservatives or any other medicines.
- * You are taking any other medicines, including medicines you buy without a prescription.
- * You have received Alkeran treatment previously.

Make sure that your doctor is aware of any of the above before you are given Alkeran.

How you are given Alkeran

Alkeran will be administered under the supervision of a doctor.

It is administered by an intravenous infusion (drip) into your veins.

Your doctor will explain to you how long your course of treatment with Alkeran will continue, and will advise you when the treatment is complete.

Use in Children

There is limited information on the use of Alkeran Injection in children.

What do I do if I receive too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have been given too much Alkeran Injection, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are having Alkeran

Things you must do

It is important that you visit your doctor regularly, so your doctor can check your progress and make sure your medicine is working.

Tell your doctor or pharmacist that you are on Alkeran if you are about to be started on any new medicines, immunisations, vaccinations or radiotherapy.

Tell your doctor if you become pregnant, are trying to become pregnant, or trying to father a child.

Tell your doctor that you are on Alkeran if you need surgery.

Alkeran Injection can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- * Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- * Be careful when using a toothbrush, tooth pick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having dental work.
- * Be careful not to cut yourself when using sharp objects such as a razor or nail cutters.
- * Avoid contact sports or other situations where you may bruise or get injured.

Things to be careful of

Be careful driving or operating machinery until you know how Alkeran affects you.

Alkeran generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Alkeran may cause dizziness, drowsiness or tiredness in some people.

What are the Side-Effects?

Check with your doctor as soon as possible if you have any problems while being given Alkeran, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines that treat cancer, Alkeran can cause some side-effects, some may be serious and need medical attention.

- * In women, periods may stop.
- * In men, sperm production may be reduced or stop.

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

Tell your doctor immediately if any of the following happen to you while you are being given Alkeran:

- * If you feel sick, vomit, develop diarrhoea or mouth ulcers.
- * If you notice any signs of jaundice (yellowing of the whites of the eyes or the skin).
- * If you start to lose weight, look pale, feel weaker, dizzy or more tired than usual.
- * If you suffer breathlessness / difficulty in breathing or coughing.
- * If you notice any signs of a skin rash, excessive skin dryness or itching, or hair loss.
- * If you notice any weakness of your muscles.
- * If you suffer pain or swelling at the injection site.
- * If you have any problems with your eyesight.
- * If you have an unusually fast heart beat.

Effects on the blood may occur. Your doctor will do regular blood tests, but you should tell him at once if you notice any signs of fever or infection, or any unexpected bruising, bleeding or signs of blood in your urine.

Tell your pharmacist or doctor if you notice any other symptoms or discomfort which are not mentioned here.

If you think you are having an allergic reaction to Alkeran, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- * wheezing

- * swelling of the lips/mouth
- * difficulty in breathing
- * hay fever
- * lumpy rash ("hives")
- * fainting

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

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

Because of the way this medicine works there is a chance it might cause other unwanted effects that may not occur until months or years after the medicine is used. These delayed effects may include certain types of cancer, such as leukaemia. Discuss these possible effects with your doctor.

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

How do I store Alkeran Injection?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Alkeran Injection in a cool, dry place where it stays below 30 degrees C, protected from light.

Do not leave in a car, on window sill or in bathroom.

Keep Alkeran Injection in its carton until time to take.

Return any unused or expired medicine to your pharmacist.

Product description

What Alkeran Injection looks like.

ALKERAN for Injection is supplied in a carton containing one single-use clear glass vial of 50mg freeze-dried

melphalan powder and one 10-mL clear glass vial of sterile diluent. The diluent is used to dissolve the powder.

Ingredients

Alkeran contains the active ingredient melphalan. Alkeran also contains povidone.

Each vial of diluent contains sodium citrate, propylene glycol, ethanol and water for injection.

Supplier

Your Alkeran Injection is supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Victoria 3155
Australia.

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 4 October 2004.

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