

# Alkeran<sup>®</sup> injection

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given ALKERAN injection?

ALKERAN injection contains the active ingredient melphalan. ALKERAN injection is used to treat multiple myeloma, a cancer of the blood.

For more information, see Section [1. Why am I being given ALKERAN injection?](#) in the full CMI.

### 2. What should I know before being given ALKERAN injection?

Do not use if you have ever had an allergic reaction to ALKERAN injection or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given ALKERAN injection?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ALKERAN injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is ALKERAN injection given?

- ALKERAN injection will be given to you under the supervision of a doctor.
- It is a sterile powder which is dissolved and then further diluted before intravenous infusion or 'drip' into a vein.
- Your doctor will decide what dose and for how long you will be given ALKERAN injection

More instructions can be found in Section [4. How do I use ALKERAN injection?](#) in the full CMI.

### 5. What should I know while being given ALKERAN injection?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ALKERAN injection.</li><li>• Tell your doctor if you become pregnant, or plan on becoming pregnant or fathering a child.</li><li>• Take precautions to reduce your risk of infections or bleeding.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not have any vaccinations without your doctor's approval</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how ALKERAN injection affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep ALKERAN injection in a cool, dry place where it stays below 30°C, protected from light.</li><li>• Keep this medicine where children cannot reach it, such as in a locked cupboard.</li></ul>

For more information, see Section [5. What should I know while being given ALKERAN injection?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects of ALKERAN injection include nausea, vomiting, diarrhoea, hair loss, muscle loss or pain, injection site pain or swelling, and reduced bone marrow cell production. Serious side effects may also occur when using ALKERAN injection. Many of these are associated with reduced bone marrow cell production, including frequent infections (symptoms include fever, sore throat, or mouth ulcers); bruising or bleeding more easily than normal (e.g. nose bleeds); unusual tiredness; looking pale; and feeling weaker, dizzy or more tired than usual. Other serious side effects include a severe allergic reaction (symptoms of which include: wheezing, swelling of lips/mouth, difficulty breathing, hayfever, lumpy rash (hives) or fainting), a yellowing of the eyes or skin, problems with eyesight, and an unusually fast heartbeat. There is also a chance that it may cause other unwanted effects months or years after this medicine is used, including certain cancers such as leukemia. Discuss these possible effects with your doctor.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Alkeran® Injection

Active ingredient(s): *Melphalan*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ALKERAN injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALKERAN injection.**

Where to find information in this leaflet:

- [1. Why am I being given ALKERAN injection?](#)
- [2. What should I know before I am given ALKERAN injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ALKERAN injection given?](#)
- [5. What should I know while being given ALKERAN injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I being given ALKERAN injection?

ALKERAN injection contains the active ingredient **melphalan**. Melphalan belongs to a group of medicines called cytotoxics.

ALKERAN injection is used to treat **multiple myeloma, a cancer of the blood**. It is thought to work by stopping cancer cells from growing and multiplying.

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

### 2. What should I know before I am given ALKERAN injection?

#### Warnings

ALKERAN injection must not be given if:

- You are allergic to tirofiban, or any of the ingredients listed at the end of this leaflet.**
  - Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
  - Always check the ingredients to make sure you can use this medicine.
- 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.
- The expiry date on the pack has passed**
- The package shows signs of tampering**

Check with your doctor if you:

- have any other medical conditions, especially the following:**
  - you have recently received or are receiving radiotherapy or chemotherapy
  - you have been vaccinated or are planning to be vaccinated
  - kidney disease
  - blood disorders
  - you have received ALKERAN treatment previously
- take any medicines for any other condition
- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

**You must not be given this medicine if you are trying to become pregnant or to father a child.**

ALKERAN injection may harm eggs and sperm. Reliable contraceptive methods must be taken to avoid pregnancy whilst you or your partner is being treated with this medicine and for at least 12 weeks after either partner stops being given it

**Mothers receiving ALKERAN injection should not breast-feed.** It is not known whether this medicine passes into the breast milk.

**You must not be given ALKERAN injection if you are pregnant or breast feeding unless you and your doctor have discussed the risks and benefits involved.**

#### Use in children

- The safety and effectiveness of ALKERAN injection in children has not been established.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may be affected by ALKERAN injection or may affect how well it works. This includes:**

- nalidixic acid
- cyclosporin
- cisplatin
- carmustine
- other cytotoxic drugs
- vaccinations with 'live' organism vaccines.

You may need to take different amounts of your medicine, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALKERAN injection.**

## 4. How is ALKERAN injection given?

### How much is given?

- Your doctor will decide what dose and for how long you will be given ALKERAN injection.
- Your doctor may order regular blood tests while you are being given ALKERAN injection in order to monitor your blood cell count and to change your dosage if necessary.

### How is it given?

- ALKERAN injection will be given to you under the supervision of a doctor.
- It is a sterile powder which is dissolved and then further diluted before intravenous infusion or 'drip' into a vein.

### If you take too much ALKERAN injection (overdose)

As ALKERAN injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

**However, if you experience any side effects after being given ALKERAN injection, tell your doctor immediately.**

Symptoms of overdose may include severe nausea and vomiting, convulsions and stomach pain.

## 5. What should I know while being given ALKERAN injection?

### Things you should do

- Visit your doctor regularly, so that they can check your progress and make sure that your medicine is working.
- **Tell any other doctor, dentist or pharmacist that you are being given ALKERAN injection, especially if you are about to be started on any new medicines or radiotherapy.**
- **Tell your doctor if you become pregnant, are trying to become pregnant, or trying to father a child.**
- **If you are about to undergo surgery or an operation, tell your doctor or surgeon that you are being given ALKERAN injection.**

This medicine 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.

- Be careful when using a toothbrush, tooth pick or dental floss.
  - **Check with your doctor before having dental work.**
  - Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums.
- 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.

### Call your doctor straight away if you:

- **Become pregnant while being treated with ALKERAN injection.**
- **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.**

### Things you should not do

- **Do not have any vaccinations without your doctor's approval.**  
ALKERAN injection may lower your body's resistance and there is a chance you might get the infection the vaccination is meant to prevent.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ALKERAN injection affects you.**

### Looking after your medicine

- **Keep ALKERAN injection in a cool, dry place where it stays below 30°C, protected from light.**
- **Keep this medicine where children cannot reach it, such as in a locked cupboard.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, return it to your pharmacist for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

**Tell your doctor as soon as possible if you do not feel well while you are being given ALKERAN injection.**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
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<ul style="list-style-type: none"> <li>• Hair loss</li> <li>• in some women, periods may stop.</li> <li>• in some men, sperm production may be reduced or stop.</li> <li>• Nausea and vomiting</li> <li>• Diarrhoea</li> <li>• Mild skin rash or itching</li> <li>• Tingling sensation</li> <li>• Persistent cough or breathlessness</li> <li>• Pain or swelling at the injection site.</li> <li>• Muscle loss and pain</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• wheezing, swelling of the lips or mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting</li> <li>• signs of infection such as fever, sore throat or mouth ulcers (infections may happen more frequently and at a higher severity due to reduced cell production by your bone marrow)bruising or bleeding more easily than normal, nose bleeds</li> <li>• unusual tiredness, looking pale, feeling weaker, dizzy or more tired than usual</li> <li>• jaundice, a yellowing of the whites of the eyes or skin</li> <li>• problems with your eyesight unusually fast heart beat.</li> </ul>	<p><b>Tell your doctor straight away, if you notice any of these serious side effects.</b></p>

**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.**

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What ALKERAN injection contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>• melphalan</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• povidone</li> <li>• sodium citrate</li> <li>• propylene Glycol</li> <li>• ethanol</li> <li>• water for injection</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ALKERAN injection looks like

ALKERAN injection is supplied in a carton containing:

- One clear glass vial containing sterile, white or off-white powder for injection
- One 10 mL clear glass vial containing a sterile, clear, colourless solution of diluent. The diluent is used to dissolve the powder.

(AUST R 79834)

### Who distributes ALKERAN injection

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos St  
St. Leonards NSW 2065  
Australia

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