

# Alkeran<sup>®</sup> tablets

## 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 using ALKERAN tablets?

ALKERAN tablets contain the active ingredient melphalan. ALKERAN tablets are used to treat some types of cancer and certain blood disorders.

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

### 2. What should I know before I use ALKERAN tablets?

Do not use if you have ever had an allergic reaction to ALKERAN 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 use ALKERAN TABLETS?](#) in the full CMI.

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

Some medicines may interfere with ALKERAN TABLETS 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 do I use ALKERAN tablets?

- The dose of ALKERAN tablets varies from patient to patient. Your doctor will decide what dose and for how long you will be taken it, and it may be adjusted throughout your treatment.
- **Swallow each tablet whole with water.**
- **Do not break, crush or chew the tablets.**

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

### 5. What should I know while using ALKERAN tablets?

<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 tablets.</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><li>• <b>Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</b></li><li>• <b>Do not use ALKERAN tablets to treat any other complaints unless your doctor says to.</b></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 tablets affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• <b>Store ALKERAN tablets in the refrigerator where the temperature is between 2-8°C. Do not freeze.</b></li><li>• Keep it where young children cannot reach it.</li><li>• <b>Keep your tablets in the bottle until it is time to take them.</b></li></ul>

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

### 6. Are there any side effects?

Common side effects of ALKERAN tablets include nausea, vomiting, diarrhoea, hair loss, muscle loss or pain, and reduced bone marrow cell production. Serious side effects may also occur when using ALKERAN tablets. Many of these are associated with reduced bone marrow cell production, including more frequent and severe infections (symptoms include fever, sore throat, or mouth ulcers); bruising or bleeding more easily than normal (e.g. nose bleeds); and 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.

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<sup>®</sup> tablets

Active ingredient(s): *melphalan*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ALKERAN tablets. **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 tablets.**

Where to find information in this leaflet:

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

## 1. Why am I using ALKERAN tablets?

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

ALKERAN tablets are used to treat some types of cancer and certain blood disorders. It interferes with the growth of cancer cells. ALKERAN may be used in combination with other medicines to treat cancer.

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

Your doctor may have prescribed it for another purpose.

## 2. What should I know before I use ALKERAN tablets?

### Warnings

Do not use ALKERAN tablets if:

- You are allergic to melphalan, 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 your infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.
- Do not take ALKERAN tablets after the expiry date printed on the label.**
- Do not take it if the bottle 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 tablets 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 tablets should not breast-feed.** It is not known whether this medicine passes into the breast milk.

**You must not be given ALKERAN tablets 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 tablets 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 tablets 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 tablets.**

## 4. How do I use ALKERAN?

### How much to take

- Your doctor will decide what dose and for how long you will be taking ALKERAN TABLETS. This depends on factors such as your weight, any pre-existing conditions and your response to the treatment.
- Your doctor may change the dose and frequency of your medicine as your condition changes. Your doctor may order regular blood tests while you are taking ALKERAN tablets in order to monitor your blood cell count and to change your dosage if necessary.
- **Take ALKERAN tablets exactly as directed by your doctor.**

### When to take ALKERAN tablets

- Your doctor will decide when you should be taking ALKERAN tablets.
- When to take ALKERAN tablets depends on factors such as the condition being treated.

### How to take ALKERAN tablets

- **Swallow each tablet whole with water.**
- **Do not break, crush or chew the tablets.**

### How long to take it for

- **Do not stop taking ALKERAN tablets or change the dose without first checking with your doctor.**
- It is important to take your ALKERAN tablets until your doctor tells you to stop.

### If you forget to use ALKERAN tablets

**Tell your doctor that you have missed a dose, and they will give you further instruction.**

**Do not take a double dose to make up for the dose you missed.**

### If you use too much ALKERAN

If you think that you have used too much ALKERAN, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using ALKERAN tablets?

### Things you should do

- **Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.** Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily
- **Visit your doctor regularly so your doctor can check your progress and make sure your medicine is working.**
- 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 taking ALKERAN tablets.**
- **Remind any doctor, dentist or pharmacist you visit that you are using ALKERAN tablets.** Especially if you are about to be started on any new medicines, immunisations, vaccinations, or radiotherapy.

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, toothpick, 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 taking ALKERAN tablets**
- 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 break, crush or chew the tablet**
- **Do not have any vaccinations without your doctor's approval.** ALKERAN tablets may lower your body's resistance and there is a chance you might get the infection the vaccination is meant to prevent.
- **Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**
- **Do not use ALKERAN tablets to treat any other complaints unless your doctor says to.**

## Use in children

- The safety and effectiveness in children has not been established

## Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALKERAN tablets affect you.

## Looking after your medicine

- **Store ALKERAN tablets in the refrigerator where the temperature is between 2 and 8 degrees Celsius. Do not freeze.**
- **Keep it where young children cannot reach it.**
- **Keep your tablets in the bottle until it is time to take them.** If you take the medicine out of the bottle it may not keep as well.

Follow the instructions in the carton on how to take care of your medicine properly.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy 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 taking ALKERAN tablets.**

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
<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>• Persistent cough or breathlessness</li><li>• Muscle loss and pain</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### 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></ul>	<b>Call your doctor straight away, or go straight to the</b>

<ul style="list-style-type: none"><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)</li><li>• 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</li><li>• unusually fast heart beat.</li></ul>	<b>Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>
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**Tell your doctor if you notice anything else that is 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 tablets contain

<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>• cellulose-microcrystalline</li><li>• crospovidone</li><li>• silica colloidal anhydrous</li><li>• magnesium stearate</li><li>• hypromellose</li><li>• titanium dioxide</li></ul>

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

### What ALKERAN tablets look like

ALKERAN tablets are white to off-white, film-coated, round tablets engraved with "GX EH3" on one side and "A" on the other. Available in bottles of 25 tablets

(AUST R 81543)

## **Who distributes ALKERAN tablets**

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos St

St. Leonards NSW 2065

Australia

This leaflet was revised in August 2024