

ALKERAN(R) tablets

Melphalan

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Alkeran tablets.

This leaflet answers some common questions about Alkeran tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Alkeran tablets against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What are Alkeran tablets used for?

Alkeran contains melphalan which belongs to a group of medicines called cytotoxics. It is used to treat some types of cancer and certain blood disorders.

Alkeran interferes with the growth of cancer cells.

Your doctor may have prescribed Alkeran tablets for another reason.

Alkeran tablets are not addictive.

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

Before you take Alkeran tablets

Do not take if:

You must not take Alkeran tablets if:

- * you have ever had an allergic reaction to melphalan or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- * the expiry date (EXP) printed on the pack has passed.
- * the packaging is torn or shows signs of tampering.
- * 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, breastfeeding or likely to father a child.

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 taking these tablets.

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.

Tell your doctor if:

You must tell your doctor if:

- * **you are allergic to foods, dyes, preservatives or any other medicines.**
- * you have recently received, or are receiving, radiotherapy or chemotherapy.
- * you have recently been vaccinated, or are planning to be vaccinated.
- * you are taking, or likely to be taking nalidixic acid, cyclosporin, cisplatin, carmustine or other cytotoxic drugs.
- * you suffer from kidney disease.
- * you suffer from a blood disorder.
- * you are planning, or likely to have surgery or dental treatment.
- * you are taking any other medicines, including medicines you buy without a prescription.
- * you have received Alkeran treatment previously.

How do I take Alkeran tablets?

Alkeran will be administered under the supervision of a doctor.

How much to take

Take Alkeran tablets as directed by your doctor or pharmacist.

The Pharmacist's label on the pack will tell you how to take Alkeran tablets. If there is something you do not understand, ask your doctor or pharmacist

The dosage is very variable and it may be changed from time to time by your doctor. If you are unsure or the dosage on the label has changed for no apparent reason, ask your doctor.

From time to time while you are taking Alkeran tablets, your doctor will want you to have a blood test. This is to check your blood cell count and to change your dose if necessary.

How to take it

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

How long to take it for

It is important to take your Alkeran tablets until your doctor tells you to stop.

Do not stop taking Alkeran tablets, or change the dose without first checking with your doctor.

Use in Children

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

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

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

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Alkeran tablets

Things you must 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.

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

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.

Things you must not do

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.

Things to be careful of

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

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

Alkeran tablets 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.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Alkeran tablets, even if the problem is not listed below.

Like other medicines, Alkeran tablets 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.

The following side-effects have been reported with Alkeran:

- * Production of bone marrow cells may be reduced. You may notice an increase in infections.
- * In women, periods may stop.
- * In men, sperm production may be reduced or stopped.

Tell your doctor if you notice any of the following:

- * If you feel sick, lose your appetite, develop diarrhoea or vomit.
- * If you develop mouth ulcers, a skin rash or itching.
- * If you have signs of fever or infection effects on the blood may occur. Your doctor will do regular blood tests.
- * If you have any unexpected bruising or bleeding.
- * 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 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 doctor immediately if you notice any of the following:

- * **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**

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.

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

How do I store Alkeran tablets?

Keep this medicine where children cannot reach it.

Store Alkeran tablets between 2 degrees C and 8 degrees C. Refrigerate. Do not freeze.

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

Keep Alkeran tablets in their bottle until it is time to take them.

Return any unused or expired medicine to your pharmacist.

Product description

What Alkeran tablets look like

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

ALKERAN tablets are supplied in bottles containing 25 and 50 tablets.

Ingredients

Alkeran tablets 2 mg contain the active ingredient melphalan. Alkeran tablets also contain microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide and macrogol 400.

Supplier

Your Alkeran tablets are supplied by:
 GlaxoSmithKline Australia Pty Ltd
 1061 Mountain Highway
 Boronia
 Victoria 3155
 Australia

Where to go for 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.

This leaflet was prepared on 4 October 2004.

The information provided applies only to: Alkeran(R) tablets 2 mg. (R)Alkeran is a registered trade mark of the GlaxoSmithKline group of companies.

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