

ALKERAN TABLETS

Melphalan (2mg)

What is in the leaflet

1. What Alkeran Tablet is used for
2. How Alkeran Tablet works
3. Before you use Alkeran Tablet
4. How to use Alkeran Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Alkeran Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What Alkeran Tablet is used for

Alkeran Tablet is used for:

- Multiple myeloma – a type of cancer that develops from cells in the bone marrow called plasma cells. Plasma cells help to fight infection and disease by producing antibodies
- Advanced cancer of the ovaries
- Advanced breast cancer
- Polycythaemia rubra vera – a disease which increases the number of red cells in your blood. This makes the blood thicken and causes blood clots. This leads to headaches, dizziness and shortness of breath

How Alkeran Tablet works

Alkeran Tablet contains a medicine called melphalan. This belongs to a group of medicines called cytotoxics (also called chemotherapy). Alkeran Tablet is used to treat cancer. It works by reducing the number of abnormal cells your body makes.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Before you use Alkeran Tablet

- When you must not take it

Do not take this medicine if:

- you have an allergy to Melphalan, or any of the other ingredients listed at the end of this leaflet
- You are breastfeeding

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Before you take Alkeran Tablet, tell your doctor or pharmacist if:

- you have had radiotherapy or chemotherapy, now or recently
- you have a kidney problem.
- You are going to have a vaccination or were recently vaccinated.
- You are using combined oral contraceptive pill.

The use of high dose Alkeran Tablet has the potential to cause acute kidney injury in patients,

especially those with underlying renal impairment.

There have been reports of acute leukaemia (a type of blood cells cancer) occurring after Alkeran treatment. Your

doctor will weigh the potential benefit of Alkeran against the risk of acute leukaemia.

Do not take Alkeran if you are planning to have a baby. This applies to both men and women. Alkeran may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner is taking these tablets and after treatment is stopped. Ask your doctor for advice.

If you are already pregnant, it is important to talk to your doctor before taking Alkeran as it can harm the baby.

Do not breast-feed while taking Alkeran. Ask your doctor for advice.

If you have not told your doctor any of the above, talk to he/she before taking Alkeran Tablet.

- Taking other medicines

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

Some medicines and Alkeran Tablet may interfere with each other.

These include:

- Other cytotoxic medicines (chemotherapy)

- Nalidixic acid (an antibiotic used to treat urinary tract infection)
- Cyclosporin (used to prevent rejection of organs or tissues following a transplant)
- In children, busulfan (chemotherapy)

These medicines may be affected by Alkeran Tablet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are going to have a vaccination, speak to your doctor before you have it. This is because some vaccines (like polio, measles, mumps and rubella) may give you an infection if you have them whilst you are taking Alkeran Tablet.

If you not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Alkeran Tablet

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

Swallow each tablet whole with water.

Do not break, crush, or chew the tablets.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

Alkeran Tablet should only be given to you by a specialist doctor who is experienced in treating cancer.

Always take Alkeran Tablet exactly as your doctor has told you.

The dose of Alkeran Tablet depends on your blood problem or cancer. Your doctor may also change your dose during your treatment, depending on your needs.

Multiple myeloma

The usual dose is 0.15mg per kilogram of your body weight each day for 4 days. This is repeated every 6 weeks.

Advanced cancer of the ovaries

The usual dose is 0.2mg per kilogram of your body weight each day for 5 days. This is repeated every 4 to 8 weeks.

Advanced breast cancer

The usual dose is 0.15mg per kilogram of your body weight each day for 5 days. This is repeated every 6 weeks.

Polycythaemia rubra vera

Initially 6 to 10mg each day for 5 to 7 days. The dose will then be reduced to 2 to 4mg each day.

The dose can sometimes be changed if you are elderly or have a kidney problem.

When you take Alkeran Tablet, your doctor will take regular blood tests. This is to check the number of cells in your blood.

- When to use it

Take each dose of Alkeran Tablet at about the same time each day.

Taking each dose of Alkeran Tablet at the same time each

day will have the best effect. It will also help you to remember when to take the medicine.

- How long to use it

Continue taking Alkeran Tablet for as long as your doctor recommends.

Prolonging treatment beyond one year does not appear to improve results.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Alkeran Tablet.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Overdose symptoms may include nausea, vomiting and diarrhea. In worse case, it may lead to decrease in production of blood cells.

While you are using Alkeran Tablet

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Alkeran Tablet.

Tell your doctor if you are pregnant, plan to become pregnant or breast-feeding.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Alkeran Tablet.

- Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take Alkeran Tablet to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

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

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Some of the very common and common side effects include:

- Nausea
- Vomiting
- Diarrhea
- Hair loss (with high dose of Alkeran Tablet)
- A drop in the number of blood cells and platelets
- Mouth ulcers
- High levels of a chemical called urea in your blood

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Alkeran Tablet

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a place where the temperature will stay between 2°C to 8°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Keep it where children cannot reach it.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

- What it looks like

Film-coated Alkeran Tablets is white to off-white, round, biconvex, one side engraved with an “A” and the other side engraved “GX EH3.

- Ingredients

Active ingredient:

- Melphalan

Inactive ingredients:

- Microcrystalline cellulose
- Anhydrous colloidal silica
- Magnesium stearate
- Opadry white
- Crospovidone
- Water

- MAL number

MAL07101257ACZ

Manufacturer

Excella GmbH, Nurnberger Strasse 12, D- 90537 Feucht, Germany.

Product Registration Holder

Aspen Medical Products Malaysia Sdn Bhd
201201020269 (1004761-W)
Unit 1302A, Level 13A, Uptown 1, 1 Jalan SS21/58, Damansara Uptown, 47400 Petaling Jaya, Selangor, Malaysia.

Date of Revision

15 Oct 2025

Serial Number

NPRA(R1/1)29032022/081