

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrALKERAN®

melphalan tablets

Read this carefully before you start taking ALKERAN and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ALKERAN.

Serious Warnings and Precautions

ALKERAN should only be prescribed by a healthcare professional experienced in the use of anti-cancer drugs.

The following serious side effects have been seen in patients taking ALKERAN:

- **Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fast heartbeat.
- **Bone Marrow Suppression:** signs and symptoms of infections (including fever, chills, sore throat, mouth ulcers), fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin lips and nail beds.
- **Lung Problems Causing Death:** suddenly worsening shortness of breath, wheezing, tiredness, possibly with a cough or fever, painful breathing.
- **Infertility in both men and women.**
- **Birth defects in babies whose mother or father was taking ALKERAN.**
- **Development of new cancers, other than the cancer you are being treated for.**

What is ALKERAN used for?

ALKERAN (melphalan tablets) is used in adults to:

- relieve symptoms caused by multiple myeloma, a cancer of the blood
- relieve symptoms caused by a type of ovarian cancer (epithelial carcinoma of the ovary) that cannot be removed by surgery

How does ALKERAN work?

ALKERAN belongs to a group of anti-cancer medicines called antineoplastic alkylating agents. These medications work by stopping cancer cells from dividing and growing.

What are the ingredients in ALKERAN?

Medicinal ingredients: melphalan

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide

ALKERAN comes in the following dosage forms:

Tablets: 2 mg

Do not use ALKERAN if:

- you are allergic to melphalan, chlorambucil or any of the other ingredients in ALKERAN.
- your disease has not responded to ALKERAN treatment.
- you are currently receiving or have recently received radiotherapy or chemotherapy.
- you have been recently treated with medicines similar to ALKERAN.
- you have low neutrophil or platelet counts (neutrophil and platelets are blood cells).
- you are breastfeeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALKERAN. Talk about any health conditions or problems you may have, including if you:

- have recently been vaccinated, or are planning to be vaccinated with a live vaccine.
- have kidney disease.

Other warnings you should know about:

- **Development of new cancers**
 - ALKERAN has been reported to cause new cancers in some patients who have been treated with the drug. If you have any concerns or notice any new symptoms talk to your healthcare professional.

- **Pregnancy and birth control**

Female patients

- If you are pregnant or able to become pregnant, there are specific risks you should discuss with your healthcare professional.
- Avoid becoming pregnant during ALKERAN treatment. It may harm your unborn baby.
- You should use effective method of birth control during ALKERAN treatment. Continue using birth control for at least 6 months after stopping treatment, or as advised by your healthcare professional.
- If you are taking oral birth control pills, you may need to switch to another birth control method to reduce your risk of getting blood clots in a vein (venous thromboembolism). Talk to your healthcare professional about birth control methods that may be right for you.
- Tell your healthcare professional right away if you become pregnant or think you may be pregnant during ALKERAN treatment.

Male patients

- Avoid fathering a child during ALKERAN treatment and for at least 6 months after stopping treatment.
- You should use effective method of birth control during ALKERAN treatment. Continue using birth control for at least 6 months after stopping treatment, or as advised by your healthcare professional.
- Tell your healthcare professional right away if your partner become pregnant during your treatment with ALKERAN.

- **Fertility**

- ALKERAN may affect your ability to have a child. If you have any concerns about this, talk to your healthcare professional.

- **Surgery**

If you need surgery, tell the healthcare professional or anaesthetist that you are taking ALKERAN.

- **Check-ups and testing**

- Your healthcare professional will do blood tests before you start treatment with ALKERAN and before each dose.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ALKERAN:

- nalidixic acid, an antibiotic used to treat bacterial infections.
- cyclosporine, used to prevent organ rejection in people who have had an organ transplant.
- busulfan, used to treat cancer.
- vaccination with live vaccines.

How to take ALKERAN:

- Always take ALKERAN tablets exactly how your healthcare professional has told you to. If you are unsure of your dose or when to take your tablets talk to your doctor or pharmacist.
- Swallow your tablets whole with a little water.
- Do NOT break, crush or chew the tablets.

Usual adult dose:

Your healthcare professional will tell you how many tablets to take and when to take them. Your dose may change based on how you are responding and your blood test results.

Thromboembolic events

- You should receive prophylaxis of venous thromboembolism (blood clots in a vein) for at least the first 5 months of treatment especially if you have additional thrombotic risk factors. Your healthcare professional will decide what measures should be taken after careful assessment of your underlying risk factors.
- Your healthcare professional will stop your ALKERAN treatment if you experience blood clots during treatment. If you have any symptoms of blood clots, tell your healthcare professional right away.
- If ALKERAN is stopped, your healthcare professional will:
 - give you treatment with anticoagulants (medicines that help prevent blood clots). You may need to continue using anticoagulants during ALKERAN treatment.
 - tell you when to restart taking ALKERAN in combination with other medicines.

Overdose:

If you think you, or a person you are caring for, have taken too much ALKERAN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose tell your healthcare professional as soon as possible. Do not double your next dose.

What are possible side effects from using ALKERAN?

These are not all the possible side effects you may feel when taking ALKERAN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- In women, periods may stop.
- In men, sperm production may be reduced or stopped.
- Nausea, vomiting, diarrhea
- Mouth ulcers or sores
- Hair loss
- Skin rash and/or itching
- Flushing

ALKERAN can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Bone Marrow Suppression: signs and symptoms of infections (including fever, chills, sore throat, mouth ulcers), fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin lips and nail beds		X	
RARE			
Allergic reaction: Swelling of the face, lips, tongue or throat, difficulty breathing, rash, hives, fast heart beat			X
Liver Problems: yellowing of the whites of eyes or the skin, dark urine, abdominal pain, nausea, vomiting, loss of appetite		X	
Lung Problems (interstitial lung disease, pneumonitis): fatal and serious with sudden worsening of shortness of breath, wheezing, tiredness, possibly with a cough or fever, painful breathing			X
UNKNOWN			
Kidney Problems: acute kidney injury (severe kidney problems),		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
confusion, itchiness or rashes, puffiness in your face and hands, swelling in your feet or ankles, urinating less or not at all, weight gain.			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store ALKERAN tablets in a refrigerator, between 2°C – 8°C.
- Keep out of reach and sight of children.

If you want more information about ALKERAN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website www.aspenpharma.ca, or by calling 1-800-330-1213.

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