

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**ALKERAN®
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 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 tablets:

Medicinal ingredient: 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:

- are pregnant or likely to become pregnant.
- are breastfeeding a baby or planning to breastfeed. It is not known if ALKERAN passes into human milk.
- have recently been vaccinated, or are planning to be vaccinated with a live vaccine.
- have kidney disease.

Other warnings you should know about:

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.

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

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
- vaccination with live vaccines-

How to take ALKERAN tablets:

- Always take ALKERAN 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 for at least the first 5 months of treatment especially if you have additional thrombotic risk factors. Your doctor will decide what measures should be taken after careful assessment of your underlying risk factors.

If you experience any thromboembolic event, tell your doctor immediately as your treatment must be discontinued and a standard anticoagulation therapy started. Your doctor will decide if you should restart melphalan in combination with lenalidomide and prednisone or thalidomide and prednisone or dexamethasone once the thromboembolic events have been managed. You should continue anticoagulation therapy during the course of melphalan treatment.

Overdose:

If you think that you have taken too much ALKERAN, contact your 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

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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/adverse-reaction-reporting.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.
- Protect from light.
- Keep out of reach and sight of children.

If you want more information about ALKERAN:

- Talk to your healthcare professional
- You may want to read this leaflet again. **Please Do Not Throw It Away** until you have finished your medicine.
- 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.html>); the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213.

This leaflet was prepared by:
Aspen Pharmacare Canada Inc.

Last revised: February 28, 2020

Trademarks are owned by or licensed to the Aspen Group of companies.

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**ALKERAN®
melphalan injection**

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 is indicated used in adults:

- to relieve symptoms caused by multiple myeloma, a cancer of the blood
- to relieve symptoms caused by a type of ovarian cancer (epithelial carcinoma of the ovary) that cannot be removed by surgery
- together with surgery to treat skin cancer (malignant melanoma)

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 injection:

Medicinal ingredient: melphalan.

Non-medicinal ingredients:

ethanol, hydrochloric acid (for pH control), povidone, propylene glycol, sodium citrate, water for injection.

ALKERAN comes in the following dosage forms:

Injection (freeze-dried): 50 mg/vial

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 (neutrophils 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:

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

Other warnings you should know about:

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.

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

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
- vaccination with live vaccines.

How to take ALKERAN injection:

ALKERAN injection will be given to you with a needle, directly into a vein (IV), by a specially trained doctor or nurse.

Usual adult dose:

Your healthcare professional will decide on your dose based on your weight and height. Your dose may change based on how well you are responding to treatment and your blood test results.

Thromboembolic events

You should receive prophylaxis of venous thromboembolism for at least the first 5 months of treatment especially if you have additional thrombotic risk factors. Your doctor will decide what measures should be taken after careful assessment of your underlying risk factors.

If you experience any thromboembolic event, tell your doctor immediately as your treatment must be discontinued and a standard anticoagulation therapy started. Your doctor will decide if you should restart melphalan in combination with lenalidomide and prednisone or thalidomide and prednisone or dexamethasone once the thromboembolic events have been managed. You should continue anticoagulation therapy during the course of melphalan treatment.

Overdose:

If you think that you have been given too much ALKERAN contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss an appointment to receive a dose of ALKERAN contact your healthcare professional as soon as possible.

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
- Mild pain and/or irritation where ALKERAN was injected
- Flushing, feelings of warmth and/or tingling
- Muscle pain, wasting, or scarring

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	
COMMON Compartment Syndrome: pain, pale skin, numbness, tingling and weakness or paralysis in the leg or arm where ALKERAN was injected		X	
RARE: Allergic Reaction: swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, rash, hives, fast heartbeat			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 suddenly worsening shortness of breath, wheezing, tiredness, possibly with a cough or fever, painful breathing			X
Injection Site Reaction: severe muscle or nerve damage, pain, redness, inflammation, tenderness, ulcers or infection at the injection site that can lead to			X

amputation			
NOT KNOWN: Severe Muscle Breakdown (rhabdomyolysis): muscle weakness, fatigue, soreness, bruising, fever, passing little or no urine, tea-coloured urine			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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/adverse-reaction-reporting.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:

- ALKERAN injection should be stored at controlled room temperature (15°-30°C).
- Protect from light.
- Keep out of reach and sight of children.

If you want more information about ALKERAN:

- Talk to your healthcare professional
- You may want to read this leaflet again. **Please Do Not Throw It Away** until you have finished your medicine.
- 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.html>); the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213.

This leaflet was prepared by:
Aspen Pharmacare Canada Inc.

Last revised: February 28, 2020

Trademarks are owned by or licensed to the Aspen Group of companies.