

MYLERAN™

Busulphan tablets 2mg

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking MYLERAN tablets.

This leaflet answers some common questions about MYLERAN tablets. It does not contain all 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 MYLERAN 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 your medicine. You may need to read it again.

What MYLERAN is used for

MYLERAN contains the active ingredient busulphan.

MYLERAN is used to treat chronic granulocytic leukaemia, polycythaemia vera, myelofibrosis, and essential thrombocythaemia. These are different types of cancer affecting the blood.

When you have blood cancer, abnormal cells are formed in the bone marrow which multiply uncontrollably, crowding out and interfering with the vital functions of normal healthy blood cells. MYLERAN helps to relieve the symptoms of these illnesses, and can make you feel better. Your doctor may have prescribed MYLERAN for another purpose.

MYLERAN belongs to a group of medicines called anti-neoplastic agents. Within this group, MYLERAN belongs to a class of medicines called alkylating agents.

MYLERAN works by interfering with the function of the bone marrow and reducing the number of cancerous blood cells which are causing you to feel unwell.

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

MYLERAN is available only with a doctor's prescription.

Before you take MYLERAN

When you must not take it

Do not take MYLERAN if:

- You have ever had an allergic reaction to busulphan or to any of the ingredients in MYLERAN listed at the end of this leaflet.
- You have taken MYLERAN before and it didn't work.
- The package is torn or shows signs of interference, or if the tablets appear broken, damaged or discoloured.
- The expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well. If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

Before you start taking MYLERAN

Tell your doctor if:

- You are pregnant or plan to become pregnant.

- MYLERAN may be harmful to an unborn baby when taken by a pregnant woman. It is recommended that you avoid becoming pregnant while taking MYLERAN.
- If you are already pregnant, your doctor will weigh up the expected benefits of MYLERAN to you against the possible risks to your unborn baby.
- You are breastfeeding or planning to breastfeed.
- The active ingredient in MYLERAN, busulphan, may pass into breast milk, so mothers taking MYLERAN should not breastfeed.
- You have recently had a course of radiotherapy or any other treatment for cancer from another doctor.
- You have any other health problems, especially kidney disease.
- You are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, please do so before taking MYLERAN.

Taking other medicines

Some medicines may affect the way others work.

Tell your doctor if you are taking any other medicines, including the oral contraceptive pill or medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

If you are taking any of the following medicines, please let your doctor know before taking MYLERAN:

- Dilantin™ (phenytoin)
- Sporanox™ (itraconazole)

- Lanvis™ (thioguanine)
- Other anticancer medicines

Your doctor will be able to tell you more about what to do when taking MYLERAN with other medicines.

Depending on the type of cancer you have, your doctor may prescribe MYLERAN in combination with other medicines used to treat cancer.

Taking MYLERAN

How much to take

Take MYLERAN exactly as your doctor has prescribed.

Your doctor will tell you how many MYLERAN tablets to take each day.

Your doctor will calculate the dose based on your weight. If you have liver or kidney problems, your doctor may decide to reduce your MYLERAN dose.

Never take more tablets than your doctor has prescribed.

Your doctor may vary your daily dose and how long you take it for depending on your type of cancer and your response to MYLERAN.

Some people need treatment with MYLERAN permanently.

Your doctor may do regular blood tests to make sure MYLERAN is working safely and effectively for you.

How to take it

Swallow tablets whole with a glass of water. Do not swallow broken tablets.

Do not crush or divide the tablets.

If you forget to take it

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

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

In case of an overdose

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much MYLERAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep phone numbers for these places handy.

If you take too many MYLERAN tablets, you could develop a red, sore mouth, nausea (feeling as if you are about to vomit), vomiting, diarrhoea and loss of appetite.

An overdose of MYLERAN could also have serious effects on some types of blood cells.

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

While you are taking MYLERAN

Things you must do

Tell all doctors, dentists and pharmacists treating you that you are taking MYLERAN.

Tell your doctor if you become pregnant while taking MYLERAN.

Tell your doctor if, for any reason, you have not taken MYLERAN exactly as prescribed. Otherwise, your doctor may think it is not working for you and change your medicine unnecessarily.

As with all medicines used to treat cancer, you should use reliable contraception when taking MYLERAN, whether you are male or female.

Tell your doctor if you feel that the tablets are not helping your condition.

Things you must not do

Do not stop taking MYLERAN or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

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

Do not drive a car or operate machinery until you know how MYLERAN affects you.

Do not take any other medicines whether they require a prescription or not without first asking your doctor or a pharmacist.

Side-Effects

All medicines can have unwanted side effects. Sometimes they may be serious, but often they are not. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have.

Be sure that your doctor or pharmacist knows as soon as possible if you do not feel well while you are taking MYLERAN.

If you think that MYLERAN is causing you to have an allergic (hypersensitivity) reaction, TELL YOUR DOCTOR IMMEDIATELY. Symptoms include:

- Severe skin rash, itching or hives.
- Swelling of the face, lips, mouth or throat.
- Difficulty breathing or swallowing.
- Fever.
- Low blood pressure (feeling dizzy and faint).

Tell your doctor if you notice any of the following:

- Diarrhoea
- Nausea (feeling as if you are about to vomit), vomiting
- Persistent dry cough

- Breathing difficulties
- Dark patches on your skin
- Dry or itchy skin, hives, rash
- Weakness
- Tiredness
- Blurred vision, visual problems
- Convulsions (fits)
- Hair loss
- Liver problems, jaundice (yellowing of the skin, eyes)
- Breast enlargement in men.
- Bruising or bleeding more easily than normal

MYLERAN may affect menstrual cycling (periods) in women. Tell your doctor if this happens.

MYLERAN may affect both male and female fertility. Your doctor will probably discuss this with you.

Your doctor can prescribe helpful medication if you develop any of the above side effects.

MYLERAN can also have side effects which affect your blood count. Your doctor will do regular blood tests to check for these.

Your doctor may also recommend that you change your dose of MYLERAN if you experience any of these side effects.

This is not a complete list of all possible side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything on this list.

Do not be alarmed by the above list of possible side effects. Many of them are uncommon. You might not experience any of them.

After taking MYLERAN

Storage

Keep your tablets in the bottle until it is time to take them.

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

Keep MYLERAN in a cool dry place where the temperature stays between 25°C.

Do not store it, or take any other medicine, in a bathroom or near a sink.

Do not leave it in a car or on window sills.

Heat and dampness can destroy some medicines.

Keep MYLERAN where young children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking MYLERAN, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What MYLERAN looks like

MYLERAN 2mg tablets are round and white. They are engraved with **GX EF3** on one side and **M** on the other.

Ingredients

Busulphan, Lactose, Starches, Erythrosine, E.127/FD&C Red, No.3 – Aluminium Lake, Povidone, Magnesium stearate

Coating

Lactose, Starches, Gelatine Magnesium stearate

Further information

Your doctor is the best person to give you advice on the treatment of your illness. You may also be able to find general information about your illness and its treatment from other sources, for example, from books in public libraries and on the Internet.

Manufacturer

MYLERAN is supplied by:

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NEW ZEALAND

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