

MYLERAN TABLETS

Busulphan (2mg)

What is in the leaflet

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

What MYLERAN Tablet is used for

MYLERAN Tablet is used to treat certain blood disorders and cancer of the blood.

Busulphan is used for certain condition of:

- Chronic granulocytic leukaemia - a disease that increases the number of white blood cells. This can cause infections and bleeding.
- Polycythaemia 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.
- Thrombocythaemia - a disease which affects platelets (blood cells which help blood to clot). There may be an increase in platelets - which causes blood clots. Or the platelets do not work properly - which causes bleeding such as nose bleeds, bleeding gums and bruising easily.

- Myelofibrosis - a disease where bone marrow (where blood cells are made) is replaced by scar (fibrous) tissue. This causes red and white blood cells to be made wrongly. This can cause tiredness, bloated stomach, bleeding, and bruising.

How MYLERAN Tablet works

MYLERAN Tablet contains a medicine called busulphan. This belongs to a group of medicines called cytotoxics. It works by reducing the amount of certain types of blood cells in your body.

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 MYLERAN Tablet

- When you must not take it

Do not take MYLERAN Tablet if you have an allergy to:

- busulphan, the active ingredient
- any of the other ingredients listed at the end of this leaflet

Do not take this medicine if you are resistance to busulphan.

Do not take MYLERAN Tablet if you are planning to become pregnant or father a child unless you and your doctor have discussed the risks and benefits involved.

MYLERAN Tablet may harm eggs and sperm. Reliable contraceptive methods must be taken to avoid pregnancy whilst you or your partner is taking this medicine.

Do not take MYLERAN Tablet if you are pregnant unless you and your doctor have discussed the risks and benefits involved. It may affect your developing baby if you take it during pregnancy.

Do not take this medicine whilst breast feeding.

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.

Tell your doctor if you have or have had any of the following conditions:

- you have recently received or are receiving radiotherapy
- you have recently been vaccinated or are planning to be vaccinated
- you are planning to have an anaesthetic

High uric acid in the urine and/or blood should be corrected before starting treatment with MYLERAN.

MYLERAN should be discontinued if lung toxicity develops.

A number of cancerous cells have been reported in people who have received MYLERAN treatment. Therefore, it should be used with careful consideration for treatment of polycythaemia vera and thrombocythaemia.

If you have not told your doctor any of the above, talk to he/she before taking MYLERAN 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 MYLERAN Tablet may interfere with each other.

These include:

- Phenytoin (used to treat and prevent fits)
- Itraconazole (for fungal infections)
- Metronidazole (for bacterial infections)
- other cytotoxic medicines (chemotherapy)
- vaccinations with 'live' organism vaccines

These medicines may be affected by MYLERAN 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 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 MYLERAN Tablet

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

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

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

- How much to use

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

The dose of busulphan depends on your blood problem or blood cancer:

Chronic Granulocytic leukaemia

The usual first dose is up to 4 mg, given as a single dose. Your doctor will then decide on the size of the next doses, based on your response.

- The treatment is normally a course which lasts for 12 to 20 weeks. You may have more than one course of treatment.
- Some people have to take busulphan long term. If you have to take it long term, the usual dose is 0.5 mg to 2 mg each day. If your dose is less than 2 mg each day, your doctor might ask you to take tablets only on certain days. Follow your doctor's instructions carefully.
- Chronic granulocytic leukaemia is rare in children and there is no

recommended dose of busulphan.

Polycythaemia vera

- The usual dose is 4 to 6 mg each day.
- The course is usually 4 to 6 weeks. This course can be repeated.
- Some people have to take busulphan long term. If you have to take it long term, the usual dose is 2 to 3 mg each day. Follow your doctor's instructions carefully.

Myelofibrosis and essential thrombocythaemia

- The usual dose is 2 to 4 mg each day.

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

Your doctor will decide what dose and for how long you will be taking MYLERAN Tablet. This depends on factors such as your weight and your response to the treatment. Your doctor may change the dose and frequency of your medicine as your condition changes.

Your doctor may order regular blood tests while you are taking MYLERAN in order to monitor your blood cell count and to change your dose if necessary.

- When to use it

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

Taking each dose of MYLERAN 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 MYLERAN Tablet for as long as your doctor recommends.

- If you forget to use it

Tell your doctor if you forget to take a dose.

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

- 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 MYLERAN Tablet.

Do this even if there are no signs of discomfort or poisoning.

Overdose symptom may include decrease in production of blood cells and platelets.

You may need urgent medical attention.

While you are using it

- Things you must do

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

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

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

- Things you must not do

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

Do not take MYLERAN 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 MYLERAN 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.

The following side effects have been reported with MYLERAN Tablet:

- production of bone marrow cells may be reduced. You may notice an increase in infections. 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
- in women, periods may stop
- in men, sperm production may be reduced or stop
- in girls, the onset of puberty may be delayed or stop.

Tell your doctor if you notice any of the following side effects:

- nausea and vomiting
- diarrhoea
- darker areas of skin
- weight loss
- jaundice, a yellowing of the whites of the eyes or the skin
- unusual tiredness, looking pale, feeling weaker or dizzy
- skin rash or itching
- hair loss

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of MYLERAN 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 at or below 25°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

If your doctor or pharmacist tells you to stop taking this

medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

White film coated tablet, white is round, biconvex and engraved with “GX EF3” on face and “M” on the other face.

- Ingredients

Active ingredient:

- Busulphan

Inactive ingredients:

- Lactose anhydrous
- Magnesium stearate
- Pregelatinised starch
- Opadry white
- Purified water

- MAL number

MAL05051050ACZ

Manufacturer

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

Product Registration Holder

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

Date of Revision

25/04/2016

Serial Number:

BPFK(R4/1)120416/00106