

MYLERAN® IV

Busulfan
60 mg/10 mL Concentrated Injection

Consumer Medicine Information

What is this leaflet?

This leaflet answers some common questions about MYLERAN IV. It does not contain all of 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 risks of you being given MYLERAN IV against the benefits they expect it will have for you.

If you have any concerns about being given MYLERAN IV, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What MYLERAN IV is used for

MYLERAN IV is used in adults, new-born infants, children and adolescents as a treatment prior to transplantation of either bone marrow or blood stem cells. It is used in combination with other chemotherapeutic drugs, namely cyclophosphamide, melphalan or fludarabine.

MYLERAN IV contains the active ingredient, Busulfan. Busulfan belongs to a group of medicines called alkylating agents.

MYLERAN IV destroys the original bone marrow before the transplant.

Your doctor may have prescribed this medicine for another use.

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

Before you are given MYLERAN IV

MYLERAN IV injection is not suitable for everyone.

When you must not be given it

- MYLERAN IV should not be given if you are allergic to busulfan or any of the other ingredients listed in this leaflet.
- MYLERAN IV should not be given if you are pregnant, or you think you may be pregnant.

Before you are given it

MYLERAN IV is a powerful cytotoxic drug that results in a huge decrease of blood cells. At the recommended dose, this is the desired effect. Therefore careful monitoring will be performed. It is possible that use of MYLERAN IV may increase the risk of suffering another malignancy in the future.

Tell your doctor if you:

- **have a liver, kidney, heart or lung problem.**
- **have a history of seizures.**
- **are currently taking other drugs.**

It may no longer be possible for you to achieve a pregnancy (infertility) after treatment with busulfan. If you are concerned about having children, you should discuss this with your doctor before treatment.

MYLERAN IV can also produce symptoms of menopause and in pre-adolescent girls it can prevent the onset of puberty.

Tell your doctor if you are pregnant, think you may be pregnant or are breast-feeding, before you receive treatment with MYLERAN IV.

Women should avoid becoming pregnant during treatment with MYLERAN IV and up to 6 months after treatment. Women should not breast-feed during their treatment with MYLERAN IV.

Men treated with MYLERAN IV are advised not to father a child during and up to 6 months after treatment.

Taking other medicines

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

MYLERAN IV may interact with other drugs.

Special caution should be taken if you use itraconazole / metronidazole (used for certain types of infections) or ketobemidone (used to treat pain), because this may increase the side-effects.

The use of paracetamol during the 72 hours prior to or with MYLERAN IV administration should be used with caution.

How MYLERAN IV is given

How much is given

In adults

The dose will be calculated according to your body weight.

The recommended dose of MYLERAN IV is up to 3.2 mg per kg of body weight per day, in combination with cyclophosphamide, melphalan or fludarabine.

In new-born infants, children and adolescents (0 to 17 years)

The recommended dose is based on body weight and may be up to 4.8 mg/kg/day.

MYLERAN IV is given by a qualified healthcare professional as a central intravenous infusion, after dilution of the individual vial. Each infusion will last 2 to 3 hours. Blood samples may be taken for testing the levels of MYLERAN IV in your blood.

MYLERAN IV will be given 1 to 4 times a day for up to 4 days prior to transplant.

Before receiving MYLERAN IV you will be given anticonvulsive drugs to prevent seizures (phenytoin or benzodiazepines) and antiemetic drugs to prevent vomiting.

Overdose

As MYLERAN IV is given to you in hospital under the supervision of your doctor, it is unlikely that you will receive an overdose.

However, if you experience any side effects after being given MYLERAN IV, tell your doctor immediately, or the Poisons Information Centre (telephone 13 1126), or go to Accident and Emergency at your nearest hospital.

Symptoms of a MYLERAN IV overdose include the side effects listed below in the **Side Effects** section, but are usually of a more severe nature.

Side Effects

Like all medicines, MYLERAN IV can have side effects. The most serious side effects may include decrease in circulation blood cell counts (intended effect of the drug to prepare you for your transplant infusion), infection, liver disorders including blocking of a liver vein, graft versus host disease (the graft attacks your body) and pulmonary complications. Your doctor will monitor your blood counts and liver enzymes regularly to detect and manage these events.

Tell your doctor nurse or pharmacist if you notice any of the following and they worry you:

- **Blood:** decrease of blood circulating cells (red and white) and platelets.
- **Infections and Infestations:** infections, fever, chills.
- **Nervous system:** insomnia, anxiety, dizziness, and depression.
- **Nutrition:** loss of appetite, decrease in magnesium, calcium, potassium, phosphate in blood and increase in blood sugar.
- **Cardiac:** increase in heart rate, increase or decrease of blood pressure, vasodilation (a state of increased calibre of the blood vessels) and blood clots.
- **Respiratory:** shortness of breath, nasal secretion (rhinitis), sore throat, cough, hiccup, nosebleeds, abnormal breath sounds.
- **Gastro-intestinal:** nausea, inflammation of the mucosa of the mouth, vomiting, abdominal pain, diarrhoea, constipation, heart burn, anus discomfort, liquid in the abdomen.
- **Hepatic:** enlarged liver, jaundice.
- **Skin:** rash, itching, loss of hairs.
- **Muscle and bone:** back, muscle and joint pain.
- **Renal:** increase in creatinine elimination, discomfort in

urination, and decrease in urine output.

- **General:** fever, headache, weakness, tiredness, chills, pain, allergic reaction, oedema, general pain or inflammation at injection site, chest pain, inflammation of the mucosa, defective teeth.
- **Investigations:** elevated liver enzymes, increased weight.

These side effects of MYLERAN IV are very common (reported in more than 1 patient out of 10).

Less common side effects (reported in 1 to 10 patients out of 100 patients) are as follows:

- **Nervous system:** confusion.
- **Nutrition:** low blood sodium.
- **Cardiac:** changes and abnormalities in heart rhythm, fluid retention or inflammation around the heart, decrease heart output.
- **Respiratory:** increase in breath rhythm, respiratory failure, alveolar haemorrhages, asthma, collapse of small portions of the lung, fluid around the lung.
- **Gastro-intestinal:** inflammation of the mucosa oesophagus, paralysis of the gut, vomiting blood.
- **Skin:** skin colour disorder, redness of the skin, skin desquamation.
- **Renal:** increase in the amount of nitrogen components in the blood stream, blood in urines, moderate renal insufficiency.

Uncommon side effects (reported in 1 to 10 patients out of 1000 patients) include:

- **Nervous system:** delirium, nervousness, hallucination, agitation, abnormal brain function, cerebral haemorrhage, and seizure.
- **Cardiac:** clotting of femoral artery, thrombosis, extra heart beats, decrease in heart rate, diffuse leak of fluid from the capillaries (small blood vessels).

- **Respiratory:** decrease in blood oxygen.
- **Gastro-intestinal:** bleeding in the stomach and/or the gut.

Febrile neutropenia, tumor lysis syndrome, thrombotic micro-angiopathy (TMA), severe bacterial, viral and fungal infections, sepsis and tooth hypoplasia have also been observed during treatment.

If you are unsure of any of these side effects please ask your doctor.

If you notice any side effects either listed or not listed in this leaflet, please notify a member of the staff taking care of you.

Other side effects not listed above may also occur in some people.

Storage

MYLERAN IV injection will be stored at 2°C-8°C in a refrigerator (do not freeze).

Sponsor

MYLERAN IV is distributed in Australia by:

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Number:

MYLERAN IV 60 mg/10 mL:
AUST R 256212

Date of leaflet:
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After using MYLERAN IV

Disposal

Any unused medicine must be disposed of appropriately by the medical staff.

Product description

What MYLERAN IV looks like

MYLERAN IV appears as a clear colourless solution. It is a sterile solution that contains no antimicrobial agent. MYLERAN IV is for single use in one patient only.

MYLERAN IV is supplied in cartons each containing 8 single-dose 10 mL clear glass vials (type I).

Ingredients

Each vial contains 10mL for a single injection. Each mL of suspension contains 6 mg busulfan.

It also contains Dimethylacetamide and Macrogol 400.