

BUSULFEX®**Busulfan****60 mg/10 mL Injection****Consumer Medicine Information****What is this leaflet?**

This leaflet answers some common questions about BUSULFEX. It does not contain all of the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given BUSULFEX against the benefits they expect it will have for you. If you have any concerns about being given BUSULFEX, ask your doctor or the medical staff looking after you.

Keep this leaflet. You may need to read it again.

What BUSULFEX is used for

BUSULFEX 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.

BUSULFEX contains the active ingredient, Busulfan. Busulfan belongs to a group of medicines called alkylating agents. BUSULFEX destroys the original bone marrow before the transplant.

Your doctor may have prescribed BUSULFEX for another use. Ask your doctor if you have any questions about why BUSULFEX has been prescribed for you.

Before you are given BUSULFEX

BUSULFEX injection is not suitable for everyone.

When you must not be given it

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

Before you are given it

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

Men treated with BUSULFEX 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. BUSULFEX may interact with other drugs.

Special caution should be taken if you use itraconazol (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 BUSULFEX administration should be used with caution.

How BUSULFEX is given

How much is given

In adults

The dose will be calculated according to your body weight.

The recommended dose of BUSULFEX 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.

BUSULFEX 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 BUSULFEX in your blood.

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

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

Overdose

As BUSULFEX 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 BUSULFEX, 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 BUSULFEX 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, BUSULFEX can have side effects. The most serious side effects of BUSULFEX therapy or the transplant procedure 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, chills, pain, allergic reaction, oedema, general pain or inflammation at injection site, chest pain, inflammation of the mucosa.
- **Investigations:** elevated liver enzymes, increased weight.
- **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 and sepsis 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.

After using BUSULFEX

Disposal

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

These side effects of BUSULFEX 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.

Product description

What BUSULFEX looks like

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

BUSULFEX 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.

Storage

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

Sponsor

BUSULFEX is distributed in Australia by:

Orphan Australia Pty. Ltd.
300 Frankston-Dandenong Road
Dandenong Victoria 3175
www.orphan.com.au

Under licence from Otsuka
Pharmaceutical Co., Ltd.

Australian patent numbers are
AU694141 and AU7829094.

This leaflet was revised in February
2010.

Australian Registration Number:
BUSULFEX 60 mg/10 mL:
AUST R 150612