BUSULFEX®

60 mg/10 mL injection

Busulfan

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BUSULFEX. It does not contain all the available information. Some of the information contained in this leaflet may not apply to you.

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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. 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 this medicine for another use.

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

Before you are given BUSULFEX

When you must not be given it

You must not be given BUSULFEX if you have an allergy to:

- busulfan, the active ingredient, or any of the other ingredients listed in this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

BUSULFEX should not be given if you are pregnant, or you think you may be pregnant or are breast-feeding.
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.

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 allergies to any other medicines, foods, preservatives or dyes.

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

- 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.

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking BUSULFEX.

Taking other medicines

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

Some medicines and BUSULFEX may interfere with each other. These include:

- itraconazole/metronidazole (used for certain types of infections)
- 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.

These medicines may be affected by BUSULFEX, or may affect how well it works. Your doctor may need to adjust your dose of BUSULFEX or of the other medicine.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking BUSULFEX.

How BUSULFEX is given

How much is given

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.

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.

If you are given too much (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 11 26), 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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BUSULFEX.

All medicines 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.

Ask your doctor or pharmacist to answer any questions you may have.

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

- decrease of blood circulating cells (red and white) and platelets.
- infections, fever, chills.
- insomnia, anxiety, dizziness, and depression.
- loss of appetite, decrease in magnesium, calcium, potassium, phosphate in blood and increase in blood sugar.
- increase in heart rate, increase or decrease of blood pressure, widening of the blood vessels (vasodilation) and blood clots.
- shortness of breath, nasal secretion (rhinitis), sore throat, cough, hiccup, nosebleeds, abnormal breath sounds.
- nausea, inflammation of the mucosa of the mouth, vomiting, abdominal pain, diarrhoea, constipation, heart burn, anus discomfort, liquid in the abdomen.
- enlarged liver, jaundice.
- rash, itching, hair loss.
- back, muscle and joint pain.
- increase in creatinine elimination, discomfort in urination, and decrease in urine output.
- headache, weakness, pain, allergic reaction, swelling (oedema), general pain or inflammation at injection site, chest pain, inflammation of the mucosa.
- elevated liver enzymes, increased weight.

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:

- confusion.
- low blood sodium.
- changes and abnormalities in heart rhythm, fluid retention or inflammation around the heart, decrease heart output.
- increase in breath rhythm, respiratory failure, bleeding in the lungs (alveolar haemorrhages), asthma, collapse of small portions of the lung, fluid around the lung.
- inflammation of the mucosa oesophagus, paralysis of the gut, vomiting blood.
- skin colour disorder, redness of the skin, peeling of the skin.
- increase in the amount of nitrogen components in the blood stream, blood in urines, moderate change in kidney function (renal insufficiency).

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

- delirium, nervousness, hallucination, agitation, abnormal brain function, cerebral haemorrhage, and seizure.
- blood clots in the femoral artery (thrombosis), extra heart beats, decrease in heart rate, diffuse leak of fluid from the capillaries (small blood vessels).
- decrease in blood oxygen.
- bleeding in the stomach and/or the gut.

Lack of white blood cells associated with high fever (febrile neutropenia), metabolic disturbances (tumor lysis syndrome), unusual bleeding or bruising under the skin (thrombotic micro-angiopathy (TMA)), severe bacterial, viral and fungal infections, sepsis and changes in tooth hardness (tooth hypoplasia) have also been observed during treatment.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After using BUSULFEX

Storage

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

Disposal

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

Product Description

What it 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.

Supplier

Otsuka Australia Pharmaceutical Pty Ltd
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Chatswood
NSW 2067, Australia

Under licence from Otsuka Pharmaceutical Co., Ltd.

Australian Registration Number

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AUST R 150612

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