

# BUSULFEX®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using BUSULFEX?

BUSULFEX contains the active ingredient busulfan. BUSULFEX is used as part of a conditioning regimen prior to transplantation of either bone marrow or blood stem cells. BUSULFEX destroys the original bone marrow before the transplant.

For more information, see Section [1. Why am I using BUSULFEX?](#) in the full CMI.

### 2. What should I know before I am given BUSULFEX?

You must not be given if you have ever had an allergic reaction to BUSULFEX, busulfan or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given BUSULFEX?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with BUSULFEX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is BUSULFEX given?

- BUSULFEX is given by a qualified healthcare professional as a central intravenous infusion
- For adults, the dose will be calculated according to your body weight
- For 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

More instructions can be found in Section [4. How is BUSULFEX given?](#) in the full CMI.

### 5. What should I know while using BUSULFEX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using BUSULFEX</li></ul>
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<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● BUSULFEX may cause dizziness in some people</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● Tell your doctor if you drink alcohol</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>● BUSULFEX injection will be stored at 2°C - 8°C in a refrigerator (do not freeze) in the Pharmacy.</li> </ul>

For more information, see Section [5. What should I know while using BUSULFEX?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects include: decrease of blood circulating cells (red and white) and platelets; infections, fever, chills; sleeplessness, 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, runny nose (rhinitis), sore throat, cough, hiccup, nosebleeds, abnormal breath sounds; nausea, inflammation of the mucosa of the mouth, vomiting, stomach pain or discomfort, diarrhoea, constipation, heart burn, anus discomfort, liquid in the stomach; enlarged liver, jaundice; rash, itching, hair loss; back, muscle and joint pain; increase in creatinine elimination, discomfort in urination, and decrease in urine output.

Serious side effects include: decreased in circulating blood cell counts; infection; liver disorders; complication relating to the lung.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# BUSULFEX®

Active ingredient(s): *busulfan*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using BUSULFEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BUSULFEX.**

**Where to find information in this leaflet:**

- [1. Why am I using BUSULFEX?](#)
- [2. What should I know before I am given BUSULFEX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is BUSULFEX given?](#)
- [5. What should I know while using BUSULFEX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using BUSULFEX?

**BUSULFEX contains the active ingredient busulfan.**

**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 destroys the original bone marrow before the transplant.

Your doctor may have prescribed this medicine for another use.

## **2. What should I know before I am given BUSULFEX?**

### **Warnings**

**You must not be given BUSULFEX if:**

- you are allergic to busulfan, or any of the ingredients listed at the end of 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
- always check the ingredients to make sure you can use this medicine.
- **you are pregnant, or you think you may be pregnant or are breast feeding.**

## **Check with your doctor if you:**

- have or had any of the following medical conditions
  - liver, kidney, heart or lung problem
  - history of seizures
- take any medicines for any other condition
- been taking other drugs

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Women should avoid becoming pregnant during treatment with BUSULFEX and up to 6 months after treatment.

Women must not breast-feed during their treatment with BUSULFEX.

It may no longer be possible for you to achieve a pregnancy 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.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with BUSULFEX and affect how it works.**

These include:

- itraconazole/metronidazole (used for certain types of infections)
- ketobemidone (used to treat pain) because this may increase the side-effects

Your doctor may ask you to stop taking medicines before receiving BUSULFEX. This may include iron chelating agents (medicines used to reduce iron levels).

Paracetamol should be used with caution during the 72 hours prior to being given, and while being given BUSULFEX.

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.



**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BUSULFEX.**

## **4. How is BUSULFEX 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

### **When BUSULFEX is given**

#### **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 a medicine to prevent seizures (anticonvulsive drugs) (for example phenytoin and antiemetic drugs to prevent vomiting).

## **If you are given too much BUSULFEX**

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, you should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

## **5. What should I know while using BUSULFEX?**

### **Things you should do**

Remind any doctor, dentist or pharmacist you visit that you are using BUSULFEX.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how BUSULFEX affects you.**

BUSULFEX may cause dizziness in some people

### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

### **Storage**

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

### **Getting rid of any unwanted medicine**

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

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gastrointestinal related</b></p> <ul style="list-style-type: none"><li>• vomiting</li><li>• stomach pain or discomfort</li><li>• diarrhoea</li><li>• constipation</li><li>• heart burn</li><li>• liquid in the stomach</li></ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"><li>• rash, itching</li></ul> <p><b>Pain related</b></p> <ul style="list-style-type: none"><li>• anus discomfort</li><li>• headache</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● general pain or inflammation at injection site</li> <li>● chest pain</li> </ul> <p><b>General well-being related:</b></p> <ul style="list-style-type: none"> <li>● sleeplessness, anxiety, dizziness, and depression</li> <li>● loss of appetite, decrease in magnesium, calcium, potassium, phosphate in blood and increase in blood sugar</li> <li>● increase in heart rate, increase or decrease of blood pressure, widening of the blood vessels (vasodilation) and blood clots</li> <li>● shortness of breath, runny nose (rhinitis), sore throat, cough, hiccup, nosebleeds, abnormal breath sounds</li> <li>● nausea</li> <li>● hair loss</li> <li>● back, muscle and joint pain</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● increase in creatinine elimination, discomfort in urination, and decrease in urine output</li> <li>● weakness, pain, allergic reaction, swelling (oedema), inflammation of the mucosa</li> <li>● elevated liver enzymes, increased weight</li> <li>● confusion</li> <li>● low blood sodium</li> <li>● changes and abnormalities in heart rhythm, fluid retention or inflammation around the heart, decrease heart output</li> <li>● increase in breath rhythm, respiratory failure, bleeding in the lungs (alveolar haemorrhages), asthma, collapse of small portions of the lung, fluid around the lung</li> <li>● inflammation of the food pipe, paralysis of the gut, vomiting blood</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● skin colour disorder, redness of the skin, peeling of the skin</li> <li>● increase in the amount of nitrogen components in the blood stream, blood in urines, moderate change in kidney function (renal insufficiency)</li> </ul> <p><b>Liver related:</b></p> <ul style="list-style-type: none"> <li>● enlarged liver</li> <li>● jaundice</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>● infections, fever, chills</li> </ul> <p><b>Inflammation related:</b></p> <ul style="list-style-type: none"> <li>● inflammation of the mucosa of the mouth</li> </ul> <p><b>Blood related:</b></p> <ul style="list-style-type: none"> <li>● decrease of blood circulating cells (red and white) and platelets</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Brain related:</b></p> <ul style="list-style-type: none"><li>• severe confusion, nervousness, hallucination, agitation, abnormal brain function, brain haemorrhage, and seizure.</li></ul> <p><b>Liver related:</b></p> <ul style="list-style-type: none"><li>• liver toxicity including blocking of a liver vein, graft versus host disease (the graft attacks your body)</li></ul> <p><b>Lung related:</b></p> <ul style="list-style-type: none"><li>• complications relating to the lung</li></ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"><li>• infection</li></ul> <p><b>Blood related:</b></p> <ul style="list-style-type: none"><li>• decrease in circulating blood cell counts (intended effect of the drug to prepare you for your transplant infusion)</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● blood clots (thrombosis) in the femoral artery (a large artery in the thigh), extra heart beats, decrease in heart rate, diffuse leakage of fluid from the capillaries (small blood vessels)</li> <li>● decrease in blood oxygen</li> <li>● bleeding in the stomach and/or the gut</li> </ul>	

The most serious side effects may include decrease in circulating 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 complications relating to the lung. Your doctor will monitor your blood counts and liver enzymes regularly to detect and manage these events.

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 else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What BUSULFEX contains**

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• Busulfan</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Dimethylacetamide</li><li>• Macrogol 400</li></ul>

<b>Potential allergens</b>	Not applicable
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Each vial contains 10mL for a single injection. Each mL of suspension contains 6 mg busulfan.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **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).

(Aust R 150612).

## **Who distributes BUSULFEX**

Otsuka Australia Pharmaceutical Pty Ltd

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Chatswood NSW 2067

Australia

Under licence from Otsuka Pharmaceutical Co., Ltd.

[www.otsuka.com.au](http://www.otsuka.com.au)

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