Busulfan APOTEX Injection

Contains the active ingredient busulfan

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all 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 taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

Busulfan APOTEX Injection 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.

Busulfan APOTEX Injection contains the active ingredient busulfan and belongs to a group of medicines called alkylating agents. Busulfan destroys the original bone marrow before the transplant.

There is no evidence that this medicine is addictive.

Your doctor may have prescribed this medicine for another reason.

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

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

Before you are given this medicine

When you must not be given it

Do not take this medicine if you have an allergy 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, throat or other parts of the body
- rash, itching or hives on the skin
- fainting or hay fever-like symptoms

Do not take this medicine if you are pregnant, think you may be pregnant or are breastfeeding.

Busulfan may affect your developing baby if you are given it during pregnancy.

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

Women must not breastfeed during their treatment with busulfan. It may pass into human breast milk.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

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 are given 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 medical conditions:

- liver, kidney, heart or lung problem
- history of seizures.

Tell your doctor if you are pregnant or plan to become pregnant.

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

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

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

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 busulfan may interfere with each other. These include:

- itraconazole/metronidazole (used for certain types of infections)
- ketobemidone (used to treat pain)
- cyclophosphamide and melphalan, often used in combination with busulfan, should not be taken for 24 hours after busulfan injection

Your doctor may ask you to stop taking medicines before receiving busulfan. 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 during busulfan administration.

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

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

How this medicine is given

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

How much is given

Your doctor will determine how much of this medicine you will be given. This will depend on your condition and whether you are taking any other medicines.

Adults

The dose will be calculated according to your body weight.

The recommended dose of busulfan 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

How it is given

Busulfan 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 busulfan in your blood.

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

Before receiving busulfan you will be given anticonvulsive drugs to prevent seizures (such as phenytoin or benzodiazepines) and antiemetic drugs to prevent vomiting

If you take too much (overdose)

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

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Accident and Emergency department at your nearest hospital.

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

While you are being given this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking busulfan.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking busulfan.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking busulfan.

It may affect other medicines used during surgery.

If you become pregnant while taking busulfan, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking busulfan.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Busulfan is a powerful cytotoxic drug (medicine to treat some cancers) that results in a huge decrease of blood cells. At the recommended dose, this is the desired effect. However, careful monitoring is needed as it is possible that use of busulfan may increase the risk of suffering another malignancy in the future.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given busulfan or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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 complications relating to the lung. Your doctor will monitor your blood counts and liver enzymes regularly to detect and manage these events.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

These side effects of busulfan are very common (reported in more than 1 patient out of 10):

- 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, vasodilation (a state of increased calibre of the blood vessels) 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.
- fever, headache, weakness, chills, pain, swelling (oedema), general pain or inflammation at injection site, chest pain, inflammation of the mucosa.
- elevated liver enzymes, increased weight.

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

- 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, skin peeling.
- 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 out of 1000 patients) include:

- severe confusion (delirium), nervousness, hallucination, agitation, abnormal brain function, cerebral haemorrhage, and seizure.
- clotting of 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 (tumour 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.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 2-8°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor stops giving you this medicine or it has passed its expiry date, the medical staff will dispose of the remaining medicine safely.

Product description

What Busulfan APOTEX looks like

Busulfan APOTEX Injection 60 mg/10 mL appears as a clear colourless solution. It is a sterile solution that contains no antimicrobial agent.

Busulfan APOTEX Injection is for single use in one patient only and is supplied in cartons each containing 8 single-dose 10 mL clear glass vials (type I).

Ingredients

Each vial contains 60 mg of busulfan as the active ingredient.

It also contains the following inactive ingredients:

- dimethylacetamide (DMA)
- macrogol 400

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Busulfan APOTEX Injection 60 mg/10 (pack of 8 glass vials): AUST R 210228

Sponsor

Apotex Pty Ltd

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