

PACKAGE LEAFLET

Package Leaflet: Information for the User

Busulfan 2mg tablets

busulfan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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What is in this leaflet:

1. What Busulfan is and what it is used for
2. What you need to know before you take Busulfan
3. How to take Busulfan
4. Possible side effects
5. How to store Busulfan
6. Contents of the pack and other information

1. What Busulfan is and what it is used for

Busulfan tablets contain a medicine called busulfan. This belongs to a group of medicines called cytotoxics (also called chemotherapy). Busulfan is used for certain blood problems and cancers of the blood. It works by reducing the number of new blood cells your body makes.

Busulfan is used for:

- **Chronic myeloid leukaemia** - a disease that increases the number of white blood cells. This can cause infections and bleeding.
- **Polycythaemia vera** a disease which increases the number of red cells in your blood. This makes the blood thicken and causes blood clots. This leads to headaches, dizziness and shortness of breath.
- **Thrombocythaemia** a disease which affects platelets (blood cells which help blood to clot). There may be an increase in platelets - which causes blood clots. Or the platelets do not work properly - which causes bleeding such as nose bleeds, bleeding gums and bruising easily.
- **Myelofibrosis** a disease where bone marrow (where blood cells are made) is replaced by scar (fibrous) tissue. This causes red and white blood cells to be made wrongly. This can cause tiredness, bloated stomach, bleeding, and bruising.
- Preparing you before **haemopoietic progenitor cell transplantation**. This is where blood cells growing in a healthy donor's bone marrow are transferred to your bone marrow to help you produce healthy cells.

Ask your doctor if you would like more explanation about these diseases.

2. What you need to know before you take Busulfan

Do not take Busulfan if:

- You are allergic (hypersensitive) to busulfan or any of the other ingredients of this medicine (listed in section 6).
- You have taken Busulfan before and it did not work.

Do not take Busulfan if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before taking Busulfan.

Warnings and precautions

Talk to your doctor or pharmacist before taking Busulfan, if:

- You have had radiotherapy or any other chemotherapy, now or recently, or if you have ever had a stem cell transplant. This is because patients taking busulfan can develop serious liver problems (hepatic veno-occlusive disease). There is an increased risk of developing hepatic veno-occlusive disease if you have had radiotherapy, more than three cycles of chemotherapy or if you have had a stem cell transplant
- You have an inherited blood problem called thalassaemia.
- You have ever had gout (painful and swollen joints caused by uric acid crystals). You may need treatment for your gout before you start taking Busulfan.
- You have a liver, kidney or lung problem.

Busulfan may cause impaired fertility in both males and females. Before starting your treatment you should talk to your doctor. Men who are planning to have children should discuss with the doctor about preserving their sperm before starting treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Busulfan.

Other medicines and Busulfan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Other cytotoxic drugs (chemotherapy) - when used with Busulfan there is a greater chance of side effects, such as breathing problems.
- Phenytoin (used to treat and prevent fits) - your doctor may need to change your phenytoin to a different medicine.
- Vaccines which contain live organisms (such as oral polio, measles, mumps and rubella) - Busulfan can make your body less able to fight infections.
- Itraconazole (for fungal infections) or metronidazole (for bacterial infections) - they can cause serious side effects if used with Busulfan.
- Cyclophosphamide (used for certain types of blood disorders) - if used with Busulfan, it is best that your first cyclophosphamide dose is given 24 hours or longer after the last Busulfan dose. This will reduce the chance of any possible side effects.
- An anaesthetic for an operation at the hospital or dentist. If so, tell your doctor or dentist that you are taking Busulfan.
- The use of Paracetamol during Busulfan administration should be used with caution.
- Deferasirox (a medicine used to remove excess iron from your body).
- Melphalan (used to treat certain cancers) – in children, it has been reported that treatment with melphalan less than 24 hours after the last busulfan treatment given by mouth may cause more problems (toxicity).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. This applies to both men and women. Busulfan may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are taking these tablets. Ask your doctor for advice. If you are already pregnant, it is important to talk to your doctor before taking Busulfan. Do not breast-feed while taking Busulfan. Ask your doctor or midwife for advice.

Busulfan contains lactose

If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take Busulfan

Busulfan should only be given to you by a specialist doctor who is experienced in treating blood problems.

Always take Busulfan exactly as your doctor has told you. It is important to take your medicine at the right times. The label on your pack will tell you how many tablets to take and how often to take them. If the label doesn't say or if you are not sure, ask your doctor, nurse or pharmacist.

- Swallow your tablets whole with a glass of water.
- **Do not break, crush or chew the tablets.**

The dose of Busulfan depends on your blood problem or blood cancer (see section 1).

- Your doctor may also change your dose during your treatment, depending on your needs.
- The dose can sometimes be changed if you are over-weight.
- If you take a high-dose of Busulfan, your doctor may also prescribe another medicine called a benzodiazepine. This will help to stop you having a fit.
- When you take Busulfan your doctor will take regular blood tests. This is to check the number of cells in your blood. Your doctor may sometimes change your dose as a result.

Chronic myeloid leukaemia The usual first dose is up to 4 mg, given as a single dose. Your doctor will then decide on the size of the next doses, based on your weight.

- The treatment is normally a course which lasts for 12 to 20 weeks. You may have more than one course of treatment.
- Some people have to take Busulfan long term. If you have to take it long term, the usual dose is 0.5 mg to 2 mg each day. If your dose is less than 2 mg each day, your doctor might ask you to take tablets only on certain days. Follow your doctor's instructions carefully.
- Chronic myeloid leukaemia is rare in children and there is no recommended dose of Busulfan.

Polycythaemia vera

- The usual dose is 4 to 6 mg each day.
- The course is usually 4 to 6 weeks. This course can be repeated.
- Some people have to take Busulfan long term. If you have to take it long term, the usual dose is 2 to 3 mg each day. Follow your doctor's instructions carefully.

Myelofibrosis and essential thrombocythaemia

- The usual dose is 2 to 4 mg each day.

Haemopoietic progenitor cell transplantation

- The medicine is usually taken on days 7, 6, 5, 4 and 3 before your transplant day (Imagine your transplant day is day 0, and that you count down the days before).
- Two days before your transplant, you will also get a medicine called cyclophosphamide. The cyclophosphamide should not be given until 24 hours have passed since your last dose of Busulfan.
 - **Adults** – The usual dose is 1 mg per kilogram of your body weight. This is taken every 6 hours.
 - **Children** – The dose is worked out according to the surface area of your body. This is taken every 6 hours.

If you take more Busulfan than you should

If you take more Busulfan than you should, tell your doctor immediately or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Busulfan

Tell your doctor. **Do not take a double dose to make up for a forgotten dose.**

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following, talk to your specialist doctor or go to hospital straight away:

- any signs of fever or infection (sore throat, sore mouth or urinary problems)
- any unexpected bruising or bleeding, as this could mean that too few blood cells of a particular type are being produced
- if you **suddenly** feel unwell (even with a normal temperature)

Talk to your doctor if you have any of the following side effects which may also happen with this medicine:

Very common (affects more than 1 in 10 people)

- a drop in the number of blood cells and platelets
- feeling sick (nausea), being sick (vomiting), diarrhoea and mouth ulcers - with high doses of Busulfan
- yellowing of the whites of the eyes or skin (jaundice) and liver damage - with high doses of Busulfan
- in women, periods may stop, fertility may be affected and the menopause may start early - with high doses of Busulfan
- in girls, the start of puberty may be delayed or prevented
- in boys and men, sperm production may be delayed, reduced or stopped and your testicles may reduce in size
- inflammation of the lung with no sign of infection - called pneumonia syndrome - with high doses of Busulfan

Common (affects less than 1 in 10 people)

- your heart may not be able to beat properly - especially if you have an inherited blood problem called thalassaemia
- inflammation of the lungs which causes breathlessness, cough and raised temperature – called pneumonitis
- hair loss (with high doses of Busulfan)
- appearance of patches of dark skin
- signs of blood in your urine and pain when passing water (bladder inflammation) - with high doses of Busulfan at the same time as taking a medicine called cyclophosphamide
- leukaemia

Uncommon (affects less than 1 in 100 people)

- in women, periods may stop and fertility may be affected and menopause may start early - with usual doses of Busulfan

Rare (affects less than 1 in 1,000 people)

- a severe drop in red blood cells which can cause tiredness, weakness, bruising and make you more likely to get infections – called aplastic anaemia
- fits or seizures - with high doses of Busulfan
- cataracts or other eye problems - after bone marrow transplantation and with high doses of Busulfan
- feeling or being sick (nausea or vomiting), diarrhoea and mouth ulcers - with usual doses of Busulfan. This can be improved by splitting the dose through the day
- jaundice (yellowing of the whites of eyes or skin) and liver damage - with usual doses of Busulfan
- hair loss (with normal doses of Busulfan)
- dry mouth and lips or other skin changes including very dry skin, itching or rash

Very rare (affects less than 1 in 10,000 people)

- muscle weakness commonly leading to drooping eye lids and difficulty in speaking or using your arms and legs – called Myasthenia gravis
- enlargement of breasts in men

- weakness, feeling very tired, weight loss, feeling sick, being sick and dark skin patches – which resembles Addison’s disease (but with the adrenal glands working correctly)

Not known (frequency cannot be estimated from the available data)

- Incomplete development of teeth

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Busulfan

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pack after ‘Exp’. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect environment.

6. Contents of the pack and other information

What Busulfan contains

The active ingredient is busulfan. Each Busulfan tablet contains 2 mg of busulfan.

The other ingredients are lactose anhydrous, pregelatinised starch, magnesium stearate, hypromellose, titanium dioxide (E171) and triacetin.

What Busulfan looks like and contents of the pack

Busulfan tablets are white, film-coated tablets and are marked with ‘GXEF3’ on one side and ‘M’ on the other. Your Busulfan tablets are in bottles of 25 or 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

Aspen Pharma Trading Limited,
3016 Lake Drive,
Citywest Business Campus,
Dublin 24, Ireland

Manufacturer:

EXCELLA GmbH & Co. KG,
Nürnberger Strasse 12,
90537 Feucht, Germany

Medical Information Enquiries

For any Medical Information enquiries about this product, please contact: 24 Hour Helpline +44(0)1748 8283 391.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: **0800 198 5000 (UK only).**

Please be ready to give the following information:

Product name: Busulfan 2 mg
Reference number: PL 39699/0042

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in October 2021.