

Package leaflet: Information for the user

Bricanyl® 500 micrograms/ml, solution for injection or infusion terbutaline sulfate

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Bricanyl Injection is and what it is used for

Bricanyl Injection contains a medicine called terbutaline sulfate. This belongs to a group of medicines called beta-agonists. These work by relaxing certain muscles. For example, they open up the airways in the lungs or relax the muscles of the womb (uterus) during pregnancy.

- Bricanyl Injection is used for breathing disorders such as asthma. It helps to relieve tightening of the chest and difficulty breathing (bronchospasm).
- Bricanyl Injection is also used in women who have unexpectedly gone into early labour (premature labour) between the 22nd and 37th week of gestation, to provide a short delay in the early delivery of the baby. You will receive Bricanyl Injection for a maximum of 48 hours. This will give your doctor or midwife time to take extra measures that will improve the health of your baby.

2. What you need to know before you use Bricanyl Injection

Do not use Bricanyl Injection:

- If you are allergic to terbutaline sulfate or any of the other ingredients of this medicine (listed in Section 6).

Do not use Bricanyl Injection if (in the treatment of premature labour):

- You are less than 22 weeks pregnant.
- You suffer from or have a known risk of developing ischaemic heart disease (disease

characterised by reduced blood supply to your heart muscle, causing symptoms such as chest pain (angina)).

- You have ever experienced miscarriage in the first two trimesters of your pregnancy.
- You are pregnant and you or your baby have certain conditions when prolongation of your pregnancy would be dangerous (such as severe high blood pressure, infection of the womb, bleeding, placenta is covering the birth canal or is detaching, or your baby has died inside the womb).
- You suffer from heart disease with palpitations (for example heart valve disorder) or longstanding lung disease (for example chronic bronchitis, emphysema) causing an increase of blood pressure to your lungs (pulmonary hypertension).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Bricanyl Injection if:

- You have had any problems with your pregnancy.
- You are diabetic. If so, you may need some additional blood sugar tests when you are given Bricanyl Injection.
- You have an overactive thyroid gland.
- You have a history of heart disease characterised by breathlessness, palpitations or angina (**see Do not use Bricanyl Injection**).

Warnings and precautions (in treatment of premature labour):

Talk to your doctor, pharmacist or nurse before using Bricanyl Injection:

- If during pregnancy, your waters have broken.
- If You have too much fluid in the lungs causing breathlessness (pulmonary oedema).
- If You have high blood pressure.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before using Bricanyl Injection.

Your doctor will monitor your heart and your unborn baby. Your doctor may also take blood tests to monitor for changes in your blood (see section 3).

Other medicines and Bricanyl Injection

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Bricanyl Injection can have an effect on the way some medicines work, and some medicines can effect how Bricanyl Injection works.

In particular tell your doctor, nurse or pharmacist if you are taking:

- Medicines for an irregular or fast heartbeat (such as digoxin).
- Other beta-blocker medicines (such as atenolol or propranolol), including eye drops (such as timolol).
- Xanthine medicines (such as theophylline or aminophylline).
- Steroid medicines (such as prednisolone).
- Water tablets, also known as diuretics (such as frusemide).
- Medicines for diabetes to reduce your blood sugar (such as insulin, metformin, or glibenclamide).
- Monoamine oxidase inhibitors (such as moclobemide).
- Tricyclic antidepressants (such as imipramine or amitriptyline).

If you are scheduled for surgery with general anaesthetics your doctor will stop the administration of Bricanyl Injection 6 hours before surgery whenever possible to protect you from adverse effects (e.g. irregular heart beat or bleeding of your womb).

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 for advice before taking this medicine.

Driving and using machines

Bricanyl Injection is not likely to affect you being able to drive or use any tools or machines.

Bricanyl Injection contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule (1 ml), that is to say essentially 'sodium-free'.

3. How to use Bricanyl Injection

You will be given Bricanyl Injection by a doctor. You will never be expected to give yourself this medicine.

For asthma and breathing problems

- You will be given the injection in one of the following ways:
 - under the skin, into a muscle, or into a vein up to four times a day.
 - or as an infusion (drip) lasting for 8 to 10 hours.
- The doctor will work out the correct dose for you. The dose for children is worked out from the child's weight.

To temporarily delay premature labour

You will never be expected to give yourself this medicine. It will always be given to you by a person who is qualified to do so after careful consideration of the balance of benefits of Bricanyl Injection to your baby and the potential untoward effects the treatment may have on you.

You will be given Bricanyl Injection by a doctor where facilities are available to continually monitor your health and that of your baby throughout administration.

- You will be given the injection in one of the following ways:
 - as an infusion (drip). The doctor will gradually increase the dose until the contractions stop. The doctor will then gradually reduce the dose to the lowest dose that stops your contractions. Your doctor will usually ask you to lie on your side during the infusion.

The following measures will be taken where necessary:

- Blood pressure and heart rate. Your doctor will consider the lowering of your dose or discontinuing Bricanyl Injection if your heart rate exceeds 120 beats per minute.
- Electrocardiography (ECG, electric activity of your heart). **Tell your doctor immediately if you experience chest pain during treatment.** If there are changes in ECG recording and you have chest pain your doctor will stop the administration of Bricanyl Injection.
- Balance of water and salts in your body. **Tell your doctor immediately if you experience coughing or shortness of breath during treatment.** If any signs indicate that

there is a build-up of fluid in your lungs (also known as pulmonary oedema) (e.g. coughing or shortness of breath), your doctor may stop the administration of Bricanyl Injection.

- Blood sugar level and the occurrence of low body pH with a build-up of lactate in your blood (also known as lactic acidosis).
- Blood potassium levels (low potassium levels may be associated with a risk of irregular heart beat).

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Important side effects to look out for:

- Allergic reactions. The signs may include a swollen face, skin rash, breathing problems, low blood pressure (feeling faint) and collapse. It is not known exactly how often this happens. **If this happens to you, tell your doctor or nurse straight away.**

Other possible side effects when used for asthma or similar conditions:

Very common (may affect more than 1 in 10 people)

- Trembling or shaking.
- Headache.

Common (may affect up to 1 in 10 people)

- Fast heart beats.
- Pounding heart beats (palpitations).
- Cramp or feeling tense.
- Low levels of potassium in your blood which may cause muscle weakness, thirst, or “pins and needles”.

Rare (may affect up to 1 in 1,000 people)

- Lactic acidosis is caused by a build-up of lactic acid in your blood. Symptoms of lactic acidosis include recurrent nausea and vomiting, abdominal pain and hyperventilation.

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

- Although it is not known exactly how often it happens, some people may occasionally experience chest pain (due to heart problems such as angina). Seek advice from your doctor if you develop these symptoms whilst taking Bricanyl Injection.
- Unusual or irregular heart beats.
- Feeling sick (nausea).
- Changes in sleeping patterns and changes in behaviour, such as feeling agitated, restless or “hyperactive”.

Important side effects to look out for when treated for premature labour:

Rare (may affect up to 1 in 1,000 people)

- Chest pain (due to heart problems such as angina). **If this happens to you, tell your doctor or nurse straight away.**

The following side effects have also been observed with all beta-agonists like Bricanyl Injection when used to delay premature labour:

Very common (may affect more than 1 in 10 people)

- Fast heart beats.
- Trembling or shaking.
- Headache.
- Feeling sick (nausea).

Common (may affect up to 1 in 10 people)

- Pounding heart beats (palpitations).
- Low blood pressure which may cause light-headedness or dizziness.
- Low levels of potassium in your blood which may cause muscle weakness, thirst, or “pins and needles”.

Uncommon (may affect up to 1 in 100 people)

- Fluid accumulation in the lungs (pulmonary oedema) which may cause difficulty breathing.

Rare (may affect up to 1 in 1,000 people)

- Unusual or irregular heartbeats.
- High levels of sugar (glucose) and/or lactic acid in your blood.
- Flushing (reddening) of the face.

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

- An increased tendency to bleeding in connection with Caesarean section.
- Changes in sleeping patterns and changes in behaviour, such as feeling agitated, restless or “hyperactive”.
- Cramp or feeling tense.

Do not be concerned by this list of possible side effects. You may not get any of them.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Bricanyl Injection

- The doctor and hospital pharmacist are responsible for storing, using and disposing of this medicine correctly.
- 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 carton and label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Keep containers in the outer carton.
- Bricanyl Injection is a clear, aqueous solution. Do not use this medicine if it does not fit this description.

6. Contents of the pack and other information

What Bricanyl Injection contains

The active substance is terbutaline sulfate. There is 0.5 mg of terbutaline sulfate per millilitre (ml).

The other ingredients are sodium chloride, hydrochloric acid and water for injection. See section 2 'Bricanyl Injection contains sodium' for more information.

What Bricanyl Injection looks like and contents of the pack

Bricanyl Injection is a clear solution for injection. It comes in packs of five glass ampoules, each containing 1 ml of solution.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Bricanyl Injection is held by AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Bricanyl Injection is manufactured by Cenexi, 52 Rue Marcel et Jacques Gaucher, 94120 Fontenay sous Bois, France.

This leaflet was last revised in September 2020.

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