# Package leaflet: Information for the user

# Bricanyl<sup>®</sup> 0.3 mg/ml Syrup terbutaline sulfate

# 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.

#### What is in this leaflet

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

# 1. What Bricanyl Syrup is and what it is used for

Bricanyl Syrup 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.

Bricanyl Syrup is used for the regular treatment of breathing disorders such as asthma. It helps to relieve tightening of the chest and difficulty breathing (bronchospasm). Bricanyl should not be used alone for the regular treatment of asthma or other breathing conditions. If you are using Bricanyl every day then your doctor should have also prescribed you another type of medication such as an "inhaled corticosteroid", which helps reduce the swelling and inflammation in your lungs.

# 2. What you need to know before you take Bricanyl Syrup

#### Do not take Bricanyl Syrup:

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Bricanyl Syrup if:

- You are pregnant and you have had problems with your pregnancy.
- You are diabetic. If so, you may need some additional blood sugar tests when you start taking Bricanyl Syrup.
- You have a history of heart disease, irregular heart rhythm or angina.
- You have an overactive thyroid gland.

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

## Other medicines and Bricanyl Syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. Bricanyl Syrup can affect the way that some medicines work and some medicines can have an effect on Bricanyl Syrup.

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

- Steroid medicines (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline).
- Beta-blocker medicines (such as atenolol or propranolol), including eye drops (such as timolol).
- Water tablets, also know as diuretics (such as frusemide).

If you are to undergo surgery with general anaesthetics it is important that you inform your doctor about all medicine you use, including Bricanyl to protect you from adverse effects (e.g. irregular heart beat).

#### 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.

Bricanyl should be used with caution at the end of pregnancy since it relaxes the womb.

#### Driving and using machines

Bricanyl Syrup is not likely to affect you being able to drive or use machines.

#### Bricanyl Syrup contains ethanol (alcohol) and sorbitol

This medicine contains small amounts of ethanol (alcohol). It contains less than 100 mg per dose.

This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

# 3. How to take Bricanyl Syrup

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The instructions on the label should remind you of what the doctor said. Do not stop taking your medicine without first discussing it with your doctor.

#### For asthma and breathing problems

The recommended starting dose for adults and the elderly is two 5 ml spoonfuls three times a day. Your doctor may then increase the dose to three 5 ml spoonfuls three times a day if necessary.

#### Use in children

The dose for children depends on the child's weight. The doctor will work out the correct dose. This is usually 0.25 ml per kg body weight three times a day. For example, if a child weighs 20 kg the dose will be 5 ml three times a day.

## Contact your doctor straight away if:

- Your breathing is getting worse.
- You often wake up at night with asthma.
- You start getting chest tightness.
- You are not getting relief from your current dose.

These signs could mean your asthma is not being controlled and you may need different or additional treatment straight away.

#### If you take more Bricanyl Syrup than you should

If you have accidentally taken too much of this medicine, contact your doctor or pharmacist for advice.

#### If you forget to take Bricanyl Syrup

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, wait until then and take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

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

## 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, stop taking Bricanyl Syrup and see a doctor straight away.
- Sudden wheezing soon after taking your dose of Bricanyl Syrup. It is not known exactly how often this happens. If this happens to you, stop taking Bricanyl Syrup and use your 'reliever inhaler' straight away. See your doctor as soon as possible as you may need to have your treatment changed.

#### Other possible side effects:

#### Very Common (may affect more than 1 in 10 people)

- Trembling or shaking.
- Headache.

#### Common (may affect up to 1 in 10 people)

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

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

- Irregular heart beats.
- Chest pain (due to heart problems such as angina). Tell your doctor if you develop this symptom whilst receiving treatment with Bricanyl Syrup, but do not stop using this medicine unless told to.
- Feeling sick (nausea).
- Mouth and throat irritation.
- Changes in sleeping patterns and changes in behaviour, such as feeling agitated, restless or hyperactive.

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

## **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u>. By reporting side effects you can help provide more information on the safety of this medicine.

# 5. How to store Bricanyl Syrup

- Keep this medicine out of the sight and reach of children.
- Do not take 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

# 6. Contents of the pack and other information

## What Bricanyl Syrup contains

The active substance is terbutaline sulfate. Each 5 ml spoonful contains 1.5 mg of terbutaline sulfate (equivalent to 0.3 mg/ml).

The other ingredients are citric acid, disodium edetate, ethanol (see section 2 "Bricanyl Syrup

contains ethanol (alcohol) and sorbitol"), glycerol, sodium hydroxide, sorbitol (see section 2

"Bricanyl Syrup contains ethanol (alcohol) and sorbitol"), sodium benzoate, essence of raspberry, and water.

## What Bricanyl Syrup looks like and contents of the pack

Bricanyl Syrup is a clear, colourless, raspberry flavoured aqueous syrup. The syrup is available in bottles of 100 ml, 300 ml and 1 litre. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisations for Bricanyl Syrup are held by AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.

Bricanyl Syrup is manufactured by Takeda Pharma Sp. z o.o., ul. Księstwa Łowickiego 12, 99 - 420 Łyszkowice, Poland.

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 nameBricanyl 0. 3 mg/ml SyrupReference number17901/0111

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

# This leaflet was last revised in: February 2017.

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