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Package leaflet: Information for the user

Bricanyl® Respules® 2.5 mg/ml Nebuliser Solution

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 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 Respules are and what they are used for
2. What you need to know before you use Bricanyl Respules
3. How to use Bricanyl Respules
4. Possible side effects
5. How to store Bricanyl Respules
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1. What Bricanyl Respules are and what they are used for

Bricanyl Respules contain a medicine called terbutaline. This belongs to a group of medicines called 'beta-agonists'. These work by relaxing certain muscles and opening up the airways in the lungs.
- Bricanyl Respules are used for asthma and other breathing problems where you have a tight chest and difficulty breathing.
- 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.
- A Respule is a small plastic container that contains a liquid. The liquid is put into a machine called a nebuliser. This machine turns the medicine into a fine mist which you breathe in through a face mask or mouthpiece.

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

Do not use Bricanyl Respules:
- If you are allergic to terbutaline or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Bricanyl Respules if:
- You have diabetes. If so, you may need some extra blood sugar tests when you start using Bricanyl Respules.
- 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 using Bricanyl Respules.

Other medicines and Bricanyl Respules

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 Respules can affect the way that some medicines work and some medicines can have an effect on Bricanyl Respules.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Steroid medicines (such as prednisolone).
- Medicines called 'xanthines' (such as theophylline).
- Medicines called 'beta-blockers' (such as atenolol or propranolol) including eye drops (such as timolol).
- Water tablets (diuretics) such as furosemide (also known 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 using this medicine.
- If you become pregnant while you are using Bricanyl Respules, talk to your doctor straight away.
- If you are using Bricanyl Respules every day rather than as needed, then Bricanyl Respules should be used with caution at the end of pregnancy since it relaxes the womb.

Driving and using machines

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

Bricanyl sodium content

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

3. How to use Bricanyl Respules

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Bricanyl Respules should be used as required rather than regularly.
Seek medical attention right away if your asthma symptoms (cough, breathlessness, wheezing or tight chest) are getting worse or if you are too breathless to speak, eat or sleep.
You must contact your doctor as soon as possible if you need higher doses of Bricanyl Respules than usual to relieve your breathing problems. You may then need extra medication to control your asthma.
If you use Bricanyl Respules more than twice a week to treat your asthma symptoms, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.
If you use a medicine against inflammation of your lungs daily, e.g., "inhaled corticosteroid", it is important to continue using it regularly, even if you feel better.
The solution in a Respule must be put into a nebuliser and made into a fine mist before it can be breathed in. It is then inhaled through a face mask or mouthpiece. Instructions for using your nebuliser are given after the section 'How much to take.

Children under 18 years should only use a nebuliser to take reliever medications under the care of a doctor with expertise in the management of asthma so that deterioration in asthma control can be detected and treated without delay.
Only use the nebuliser recommended by your doctor and supervise your child while they are using the nebuliser.

Seek urgent medical assistance if the nebulised medication is not working, even if there is short-term recovery following use of prescribed nebulised medication.

How much to take

The recommended dose is:
- Adults: 1 to 2 Respules, 2 to 4 times a day
- Children over 8 years: 1 Respule, 2 to 4 times a day
- Younger children are usually prescribed lower doses.

Instructions for using Bricanyl Respules

1. Break off a Respule from the strip. Leave the rest in the foil envelope.
2. Hold upright. Twist off the top of the Respule to open.
3. Place the open end of the Respule firmly inside the nebuliser cup. Squeeze slowly to put the liquid in the cup.
4. Throw the empty Respule away. Put the top back on the nebuliser cup.
5. Connect the top of the cup to the face mask or mouthpiece.
6. Connect the bottom of the cup to the air pump. The air pump should be connected to the compressor unit.
7. Turn on the nebuliser and breathe in the mist calmly and deeply using the face mask or mouthpiece. If you are using a face mask, make sure the face mask fits tightly.
8. You will know when your treatment is complete because the fine mist will stop coming out of your mask or mouthpiece.
9. How long it takes to nebulise all the medicine depends on the type of equipment you use. It will also depend on the amount of medicine to be used.
10. After each use, you must wash the nebuliser cup and mouthpiece (or face mask) in warm soapy water and rinse well. After washing, dry these parts by turning on the compressor and allowing air to blow through them.

Text area for artwork

Talk to your doctor straight away if:

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

These are signs that your asthma is not being controlled. You may need a different or additional treatment straight away.

If you use more Bricanyl Respules than you should

If you use more Bricanyl Respules than you should, contact your doctor or pharmacist.

If you forget to use Bricanyl Respules

- if you forget to have a dose, have it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Bricanyl Respules

Do not stop taking your medicine without first discussing it with your doctor.

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 how often this happens. **If this happens to you, stop using your nebuliser and see a doctor straight away.**
- Sudden wheezing soon after inhaling your dose of Bricanyl Respules. It is not known how often this happens. **If this happens to you, stop using Bricanyl Respules and see a doctor straight away.**

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 beats (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 available data)

- Unusual or 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 Respules, 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.
- 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.

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. 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 Bricanyl Respules

- Keep this medicine out of the sight and reach of children.
- Once a foil envelope has been opened, the Respules inside should be used within 3 months. **Note:** It is best to mark the opening date on the foil envelope to help you remember.
- Once you have opened a single Respule, any remaining product cannot be regarded as sterile. This must be considered if the intention is to use the remaining content at a later occasion.
- Each single Respule should be used within 24 hours after it is opened. After this time the Respule and any remaining contents should be thrown away.
- Do not store above 30°C. Store Bricanyl Respules in their original carton and foil, and out of direct sunlight.
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bricanyl Respules contains

The active substance is terbutaline sulfate. Each Bricanyl Respule contains 5 mg of the active ingredient, terbutaline sulfate (equivalent to 2.5 mg/ml).
The other ingredients are sodium chloride, disodium edetate, hydrochloric acid and water.

What Bricanyl Respules look like and the contents of the pack

Respules are single dose plastic units containing 2 millilitres (ml) of solution.
The solution must be nebulised (made into a fine mist) before it can be breathed in.
Bricanyl Respules are available in boxes of 20.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Bricanyl Respules is held by AstraZeneca UK Limited,
1 Francis Crick Avenue,
Cambridge,
CB2 0AA,
UK.

Bricanyl Respules are manufactured by AstraZeneca AB, SE-151 36, Södertälje, Sweden.

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
Bricanyl Respules 2.5 mg/ml Nebuliser Solution
Reference number
17901/0114

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

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