

Package Leaflet: Information for the User

Respontin[®] Nebules[®]

ipratropium bromide

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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Respontin Nebules are and what they are used for
- 2 What you need to know before you use Respontin Nebules
- 3 How to use Respontin Nebules
- 4 Possible side effects
- 5 How to store Respontin Nebules
- 6 Contents of the pack and other information

1 What Respontin Nebules are and what are they used for

Respontin Nebules contain a medicine called ipratropium. This belongs to a group of medicines called 'relievers' or bronchodilators. They relax the muscles in the airways of your lungs. This helps to:

- open your airways
- relieve chest tightness, wheezing and coughing so that you can breathe more easily.

Respontin Nebules are used to treat:

- asthma
- other breathing difficulties in adults, such as Chronic Obstructive Pulmonary Disease (COPD).

They are usually given to people who have these conditions when other treatments have not helped enough.

A Nebule[®] is a small plastic container that contains a liquid. The liquid is put into a machine called a nebuliser. This machine makes a fine mist for you to breathe in through a face mask.

2 What you need to know before you use Respontin Nebules

Do not use Respontin Nebules if:

- you are allergic to ipratropium bromide or any of the other ingredients of this medicine (listed in section 6)
- you are allergic (hypersensitive) to atropine.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before using Respontin Nebules.

Take special care with Respontin Nebules

Talk to your doctor, nurse or pharmacist before using Respontin Nebules if:

- you have difficulty passing water because your prostate gland is enlarged
- you have cystic fibrosis
- you suffer from a problem caused by too much pressure in your eye (glaucoma). You need to make sure the mist from the nebuliser does not get in your eyes.

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

Other medicines and Respontin Nebules

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 if you are taking any of the following:

- medicines for breathing problems called 'beta-agonists' such as salbutamol
- medicines for breathing problems called 'xanthine preparations' such as theophylline or aminophylline.

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.

Driving and using machines

You may feel dizzy or have difficulty in focusing or have blurred vision whilst taking Respontin Nebules. If this happens do not drive or use any tools or machines.

3 How to use Respontin Nebules

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

- **do not inject or swallow the liquid.** Respontin Nebules should only be inhaled using your nebuliser
- **do not let the liquid, or the mist produced by the nebuliser get into your eyes.** You can wear glasses or goggles to protect them
- your doctor, nurse or pharmacist should show you how to use your medicine
- each small plastic container (Nebule) contains some liquid
- the liquid is put into a nebuliser. This makes a fine mist for you to breathe in through a face mask
- you must use your nebuliser in a well-ventilated room as some of the mist will be released into the air and may be breathed in by others.

Adults (including the elderly) and children over 12 years old

- the usual dose is the contents of 1 to 2 single dose units (250-500 micrograms), three to four times a day
- for acute attacks of breathlessness use 2 single dose units (500 micrograms)
- if breathlessness does not go away or gets worse consult your doctor.

Children 6 to 12 years old

- 1 single dose unit (250 micrograms) up to a total daily dose of 4 single dose units (1 mg)
- the time between doses should be decided by your doctor.

Children 0 to 5 years for treatment of acute asthma only

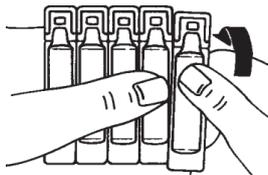
- ½ to 1 single dose unit (125-250 micrograms) up to a total daily dose of 4 single dose units (1 mg)
- the time between doses should be not be less than 6 hours.

When children are using this medicine they must be supervised by a responsible adult.

Do not use your nebuliser to take Respontin Nebules and 'disodium cromoglycate inhalation solutions' which have the preservative 'benzalkonium chloride' at the same time.

Using your Nebules

1. your Nebules are in a foil pack. Do not open the pack until you need to use them
2. cut the pack along the dotted line and take out the Nebules
3. hold the strip of Nebules in one hand, with your other hand hold the last Nebule in the row
4. twist the Nebule downwards and away from you



5. return the remaining Nebules to the foil pack and replace it in the box
6. hold the top of the Nebule you have just removed. Twist the body to open it



7. put the open end of the Nebule into the nebuliser bowl and squeeze slowly



8. assemble the nebuliser and use it as directed.

Diluting your Nebules

You may need to dilute the liquid in the Nebule. This depends on the nebuliser you use and how long you are meant to inhale for.

- **do not dilute the contents of a Nebule unless you are told to by your doctor**
- if your doctor has told you to dilute the solution, empty the contents of the Nebule into the nebuliser bowl
- add the amount of sterile sodium chloride 0.9% solution your doctor has told you to use
- put the top on the nebuliser bowl and shake gently to mix the contents.

If dilution is necessary then only sterile sodium chloride 0.9% solution should be used.

After use

- use a fresh Nebule for each dose. Only open a new one when you are ready to use it. If there is any liquid left over, throw it away. Do not save it to use again
- throw away any solution remaining in the nebuliser bowl
- clean your nebuliser in the recommended way.

If you use more Respontin Nebules than you should

If you use more medicine than you should, the following effect may happen:

- fast or irregular heart beats.

If you think you have used too much talk to a doctor. Take the medicine pack with you.

If you forget to use Respontin Nebules

- If you become wheezy, inhale your missed dose
- If you are not wheezy, do not worry, just inhale the next dose when it is due
- If it is time for your next dose, skip the missed dose, do not use a double dose (two doses at once) to make up for a forgotten dose.

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

4 Possible side effects

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

Stop using Respontin Nebules and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- If after using Respontin Nebules you are wheezy or have other difficulties in breathing, do not use any more (unless you have been told to by your doctor).
- Allergic reactions – the signs may include skin rash and itching (may affect up to 1 in 100 people). In severe cases the signs include swelling of your mouth and face, sudden difficulties in breathing and reduction of your blood pressure. Tightening of your throat (may affect up to 1 in 100 people).
- Palpitations (fast or uneven heart beats) or quickening of the heart rate (may affect up to 1 in 100 people).
- Increased heart rate or irregular heart rhythm such as atrial fibrillation (may affect up to 1 in 1000 people).

Stop using this medicine and see your doctor straight away if you have any of these side effects.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Headache, dizziness.
- Dry mouth, feeling sick (nausea), stomach upset or discomfort.
- Cough and throat irritation when you have just used Respontin Nebules.

Uncommon (may affect up to 1 in 100 people)

- Itching, skin rash.
- Unexpected tightness of the chest, swelling of the throat, dry throat.
- Blurred vision, dilated pupils, glaucoma, painful, stinging, red or swelling of the eyes, see colours or lights.
- Diarrhoea, constipation or being sick.
- Mouth or lip sores.
- Problems passing water (urine), especially if you already have problems passing urine.

Rare (may affect up to 1 in 1000 people)

- Difficulty focusing.
- Nettle rash (urticaria).

If any of the liquid or mist accidentally gets into your eyes you may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If affected, do not drive or use any tools or machines. If you get problems with your eyes at any other time, talk to your doctor for advice.

If the relief of wheezing or chest tightness is not as good as usual or does not last for as long as usual, tell your doctor as soon as possible. It may be that your chest condition is getting worse and perhaps you may need an extra medicine.

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

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

5 How to store Respontin Nebules

- Keep this medicine out of the sight and reach of children.
- Keep Respontin Nebules out of the light and in the foil pack.
- When you open a foil pack:
 - Note the date
 - Add 4 weeks to this date. This is the new 'discard after' date.
 - There is a space on the foil pack lid to write the 'discard after' date.
 - Do not use any unused Respontin Nebules from that foil pack after this 'discard after' date.

