

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Read this entire leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms 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.

### **In this leaflet:**

1. What Salbutamol Pressurised Inhalation BP 100mcg is and what it is used for
2. What you need to know before you take Salbutamol Pressurised Inhalation BP 100mcg
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### **1. WHAT SALBUTAMOL PRESSURISED INHALATION BP 100MCG IS AND WHAT IT IS USED FOR**

Salbutamol Pressurised Inhalation BP 100mcg belongs to a group of medicines called fast acting bronchodilators.

- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Salbutamol Pressurised Inhalation BP 100mcg is used to treat breathing problems in people with asthma and similar conditions. This includes relieving and preventing asthma brought on by exercise or other “triggers”. These are things, which bring on asthma symptoms in some people. Common triggers include house dust, pollen, cats, dogs and cigarette smoke.

Salbutamol Pressurised Inhalation BP 100mcg contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Salbutamol Pressurised Inhalation BP 100mcg. This will make no difference to how your medicine works.

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### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SALBUTAMOL PRESSURISED INHALATION BP 100MCG

#### **Do not take Salbutamol Pressurised Inhalation BP 100mcg if:**

- you are allergic to salbutamol sulfate or any of the other ingredients of this medicine

#### **Warnings and precautions**

Talk to your doctor, nurse or pharmacist before taking Salbutamol Pressurised Inhalation BP 100mcg if:

- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your doctor may start or increase a medicine to control your asthma such as an inhaled corticosteroid.
- you have high blood pressure
- you have an overactive thyroid gland
- you have a history of heart problems such as an irregular or fast heartbeat or angina.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.

#### **Other medicines and Salbutamol Pressurised Inhalation BP 100mcg**

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

Remember to take this medicine with you if you have to go to hospital.

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

- medicines for an irregular or fast heartbeat
- other medicines for your asthma.

#### **Salbutamol Pressurised Inhalation BP 100mcg with food and drink**

You can take Salbutamol Pressurised Inhalation BP 100mcg at any time of day, with or without food.

#### **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, nurse or pharmacist for advice before taking this medicine.

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### **Driving and using machines:**

Salbutamol Pressurised Inhalation BP 100mcg is not likely to affect you being able to drive or use any tools or machines.

### **3. HOW TO TAKE SALBUTAMOL PRESSURISED INHALATION BP 100mcg**

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

#### **Adults and adolescents aged 12 years and over**

- to relieve asthma - One or two puffs.
- to prevent asthma - Two puffs 10-15 minutes before exercise or exposure to a “trigger”.
- for regular treatment - Two puffs up to 4 times a day.
- the maximum dose is 8 puffs in a 24 hour period.

#### **Children under 12 years of age**

- to relieve asthma - One puff. Two puffs if required.
- to prevent asthma - One puff 10-15 minutes before exercise or exposure to a “trigger”. Two puffs if required.
- for regular treatment - Two puffs up to 4 times a day.
- the maximum dose is 8 puffs in a 24 hour period.

#### **Instructions for use**

- Salbutamol Pressurised Inhalation BP 100mcg produces a fine mist, which you inhale through your mouth into your lungs.

Your doctor, nurse or pharmacist should show you how to use your inhaler. If you are not sure ask your doctor, nurse or pharmacist.

- Each Salbutamol Pressurised Inhalation BP 100mcg canister provides 200 puffs.

Do not use your inhaler more often than the doctor told you to. Tell your doctor if your medicine does not seem to be working as well as usual, as your chest problem may be getting worse and you may need a different medicine.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

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### **Testing your inhaler**

**1** When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

**2** To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release two puffs into the air. If you have not used the inhaler for 5 days or more, shake it well and release two puffs of medicine into the air.

### **Using your inhaler**

It is important to start to breathe as slowly as possible just before using your inhaler.

**1** Stand or sit upright when using your inhaler.

**2** Remove the mouthpiece cover. Check inside and outside to make sure that the mouthpiece is clean and free of objects.

**3** Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.

**4** Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.

**5** Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.

**6** Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and Deeply.

**7** Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.

**8** If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

**9** After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position. Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together.

Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece.

Your doctor, nurse or pharmacist will be able to advise you.

### **Cleaning your inhaler**

To stop your inhaler blocking, it is important to clean it at least once a week.

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To clean your inhaler:

- Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
- Rinse the plastic casing thoroughly under warm running water.
- Dry the plastic casing thoroughly inside and out.
- Replace the metal canister into the plastic casing and put on mouthpiece cover.

Do not put the metal canister in water.

### **If you take more Salbutamol Pressurised Inhalation BP 100mcg than you should**

If you take more than you should, talk to a doctor as soon as possible.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky.
- hyperactivity

These effects usually wear off in a few hours.

### **If you forget to take Salbutamol Pressurised Inhalation BP 100mcg**

- If you forget a dose, take it as soon as you remember it.
- However, if it is 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 taking Salbutamol Pressurised Inhalation BP 100mcg**

Do not stop taking Salbutamol Pressurised Inhalation BP 100mcg without talking to your doctor.

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

## **4. POSSIBLE SIDE EFFECTS**

**If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Allergic Reactions** (may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking Salbutamol Pressurised Inhalation BP 100mcg and see a doctor straight away.

Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

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### **Talk to your doctor as soon as possible if:**

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these may affect up to 1 in 10 people.

If any of these happen to you, talk to your doctor as soon as possible. **Do not stop using this medicine unless told to do so.**

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

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

- feeling shaky
- headache.

#### **Uncommon** (may affect up to 1 in 100 people)

- mouth and throat irritation
- muscle cramps.

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

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation).

#### **Very rare** (may affect up to 1 in 10,000 people)

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

#### **The following side effects can also happen but the frequency of these are not known:**

- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs.

Do not stop using this medicine unless told to do so.

#### **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.

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

#### **If you think this medicine is not working well enough for you**

If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra doses of Salbutamol Pressurised Inhalation BP 100mcg unless your doctor tells you to.

## **5. HOW TO STORE SALBUTAMOL PRESSURISED INHALATION BP 100MCG**

Keep this medicine out of the sight and reach of children.

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- Store below 30°C. Protect from frost and direct sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not puncture, break or burn it even when apparently empty.
- Do not use this medicine after the expiry date, which is stated on the label and carton after 'EXP'. 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 to protect the Environment.

**6. FURTHER INFORMATION**

**What Salbutamol Pressurised Inhalation BP 100mcg contains**

The active ingredient is Salbutamol.

The other ingredients are:

Propellant HFA 134a.

**What Salbutamol Pressurised Inhalation BP 100mcg looks like and contents of the pack**

Pressurised metered dose inhaler containing suspension aerosol filled in aluminium canister fitted with suitable metered valve. There should be no sign of physical damage or leakage.

**STORAGE**

Store below 30°C .Do not freeze.

Protect from frost and direct sunlight.

Store the inhaler with the mouthpiece down.

**PRESENTATION**

Each carton contains a labeled metal container coupled with plastic actuator and a patient information leaflet

**MANUFACTURED BY**

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