

# SALBUTIS (SALBUTAMOL INHALATION AEROSOL 100MCG/DOSE CFC FREE)

Salbutamol sulphate (100mcg/dose)

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## **What SALBUTIS is used for**

SALBUTIS provides short-acting (4 to 6 hours) bronchodilatation with fast onset (within 5 minutes) in reversible airways obstruction.

It is particularly suitable for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).

SALBUTIS is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.

## **How SALBUTIS works**

Salbutamol is a selective  $\beta_2$ -adrenoceptor agonist. At therapeutic doses it acts on the  $\beta_2$ -adrenoceptors of bronchial muscle providing short acting (4-6 hours) bronchodilatation with a fast onset (within 5 minutes) in reversible airways obstruction.

## **Before you use SALBUTIS**

### -When you must not use it

- If you are allergic (hypersensitive) to salbutamol sulphate or the other ingredient HFA 134a.

### - Before you start to take it

Check with your doctor, nurse or pharmacist if:

- 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.

### - Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any 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.

## **How to use SALBUTIS**

### -How much to use

### **In acute bronchospasm:**

Adult dosage: 100 to 200 mcg daily.  
Children dosage: 100 mcg daily. If required, the dose can be increased to 200mcg.

### **Prevention of exercise-induced bronchospasm:**

Adult dosage: 200mcg daily before exertion.  
Children dosage: 100 mcg daily before exertion. If required, the dose can be increased to 200mcg.

### **In Chronic therapy:**

Adult dosage: Up to 200mcg four times daily.  
Children dosage: Up to 100mcg four times daily

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue taking Salbutis for as long as your doctor recommends.

### - If you forget to use it

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 use too much (overdose)

The expected symptoms with overdose are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the symptoms listed under ADVERSE REACTIONS, e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and sleeplessness. Hypokalemia may also occur.

The preferred antidote for overdose with salbutamol is a cardioselective  $\beta$ -blocking agent, but  $\beta$ -blocking drugs should be used with caution in patients with a history of bronchospasm.

## **While you are using it**

### - Things you must do

### **Testing your inhaler**

- 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.
- To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release a dose into the air. If you have not used the inhaler for a week or more, release two doses of medicine into the air.

### **Using your inhaler properly**

- Remove the cover from the mouthpiece and shake the inhaler vigorously.
- Holding the inhaler as shown, breathe out gently (but not fully) and then place the mouthpiece in the mouth immediately and close your lips around it. After starting to breathe in slowly and deeply through your mouth, press the inhaler firmly, as shown, to release it and continue to breathe in.
- Hold your breath for 10 seconds, or as long as is comfortable, before breathing out slowly.

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- If you are to take a second inhalation you should wait at least one minute before repeating steps 2, 3 and 4.
- After use, replace the cover on the mouthpiece.

## Cleaning your inhaler

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

To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.
- Replace the mouthpiece cover.

Do not put the metal canister in water.

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 doses to take and how often to use your inhaler.

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

### - Things you must not do

Do not use your inhaler more often than the doctor told you to.

Do not stop taking this inhaler without talking to your doctor.

The canister is pressurised. Do not incinerate or expose to heat. Do not puncture even when empty.

### - Things to be careful of

It should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders,

hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines.

The daily dosage must be controlled, if the therapeutic effect is not evident, the other therapies should be considered.

It will develop tolerance in a prolonged administration period.

It is not appropriate to take such  $\beta$  adrenergic blocking agents as propranolol while using SALBUTIS.

## Side effects

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

The following side effects may happen with this medicine: Xerostomia, cough, vomiting, Dizziness and palpitation.

Talk to your doctor as soon as possible. If any of above side effect happens to you, talk to your doctor as soon as possible.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of SALBUTIS

### - Storage

Store below 30°C. Protect from frost and direct sunlight.

As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold. The canister should not be broken, punctured or burnt, even when apparently empty.

Keep medicines out of reach of children.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will you protect the environment.

## Product Description

### - What it looks like?

Salbutamol inhalation aerosol is a kind of white or slight yellow suspension mixed with just right quantity of propellant and kept in a pressurised canister with a metered valve system.

### - Ingredients

- Active ingredient:  
Salbutamol sulphate

- Inactive ingredients:  
Ethanol (absolute), oleic acid, HFA 134a propellant

- MAL Number: -  
MAL11080001AZ

## Manufacturer

Jewim Pharmaceutical (Shandong) Co., Ltd  
Taian Hi-Tech Industrial Development Zone, CHINA

## Product Registration Holder

MEDISPEC (M) SDN. BHD.  
No. 55 & 57, Lorong Sempadan 2 (Off Boundary Road) 11400 Ayer Itam, Penang, Malaysia

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