SALBUTIS (SALBUTAMOL INHALATION AEROSOL CFC FREE)

Salbutamol sulphate (100mcg/dose)

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What SALBUTIS is used for

SALBUTIS is used 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 to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).

How SALBUTIS works

Salbutamol works by relaxing the muscles of the airways of the lungs, to help improve the ease of breathing in people with reversible obstructive airway disease.

Before you use SALBUTIS

- When you must not use it
- you are allergic (hypersensitive) to salbutamol sulphate or any of the inactive ingredients.
- For premature labour
- · For threatened abortion

Pregnancy and lactation

Do not use SALBUTIS if you are pregnant, trying to get pregnant or think you may be pregnant.

As salbutamol is probably secreted in breast milk, do not use SALBUTIS if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor before you start to use this medicine if you:

heart disease or high blood pressure;

- diabetes:
- an overactive thyroid

Important points to remember while you are using this medicine:

- 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 use 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.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop especially propranolol (use for high blood pressure)

How to use SALBUTIS

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

In rapid, short term bronchospasm (difficulty in breathing):

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

Prevention of allergen or exerciseinduced bronchospasm (difficulty in breathing):

Adult dosage: 200mcg daily before exertion.

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

In long term 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

Consult your doctor or pharmacist on what you should do if you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. The following effects may happen:

- your heart beating faster than usual
- you feel shaky.
- nausea, dizzy, tired
- •dry mouth
- headache
- chest pain
- increase or decrease blood pressure
- seizures

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking SALBUTIS.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give SALBUTIS to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Store SALBUTIS away from moisture and heat. Keep the medicine canister away from high heat, such as open flame or in a car on a hot day. The canister may explode if it gets too hot.

It will develop tolerance in a prolonged use period.

Side effects

Like all medicines, SALBUTIS can cause side effects, although not everybody gets them. The following side effects may happen with this medicine: dry mouth, pounding of strong heart beat, cough, dizziness and vomiting.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)

Storage and Disposal of SALBUTIS

- Storage

Keep out of the reach and sight of children.

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

- <u>Disposal</u>

The canister is pressurized and should not be punctured or burnt even if it seems empty. Medicines should not be disposed via wastewater or household waste. If your doctor decides to stop treatment, return the inhaler to your doctor or pharmacist for safe disposal. These measures will help to protect the environment.

Product Description

- What it looks like

SALBUTIS is a kind of white or slight yellow suspension mixed with just right quantity of propellant and kept in a pressurized canister with a metered valve system.

- Ingredients

- Active ingredient: Salbutamol (as sulphate)
- Inactive ingredients: Oleic acid Absolute ethanol HFA 134a
- <u>MAL number:</u> MAL11080001AZ

Manufacturer

Jewim Pharmaceutical (Shandong) Co., Ltd

Tai'an High-Tech Industrial Development Zone, Shandong Province, China.

Product Registration Holder

Medispec (M) Sdn Bhd 55&57, Lorong Sempadan 2, (Off Boundary Road), 11400 Ayer Itam, Penang.

Date of revision

22.3.2018

Serial Number:

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How to Use Your Inhaler Properly









- 1. Remove the cover from the mouthpiece and shake the inhaler vigorously.
- 2. Holding the inhaler as shown, breathe out gently (but not fully) and then immediately...
- 3. Place the mouthpiece in the mouth and close your lips around it, press the

- inhaler firmly, as shown, to release it and continue to breathe in.
- 4. Hold your breath for 10 seconds, or as long as is comfortable, before breathing out slowly.
- 5. If you are to take the second inhalation you should wait at least one minute before repeating steps 2, 3 and 4.
- 6. After use, replace the cover on the mouthpiece.

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.

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.