SALMODIL SYRUP

Salbutamol sulphate/Bromhexine hydrochloride (2mg/4mg per 5ml)

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What SALMODIL is used for

SALMODIL is a bronchodilator (helps open the airways in the lungs) with mucolytic (to breakdown mucus) expectorant for clearance of viscid purulent mucus in acute and chronic bronchiectasis (abnormal widening of the airways) and whooping cough.

How SALMODIL works

It contains salbutamol, which works by relaxing the muscles of the airways of the lungs, and facilitates in breathing. It also contain bromhexine, which works by thinning the mucus in the airways, thus making the mucus less sticky and it also facilitates the removal of the mucus.

Before you use SALMODIL

-When you must not use it

Tell your doctor before using SALMODIL if you

- Are allergic to Salbutamol or Bromhexine or any other ingredients listed at the end of this leaflet.
- have thyrotoxicosis (excessive amount of thyroid hormone).
- have severe cardiovascular disease (disease of the heart or blood vessels).
- have angina (chest pain).
- have peptic ulcer (ulcers in the lining of the stomach or first part of the small intestine.

-Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant, planning to get pregnant or are breastfeeding. SALMODIL should only be used during pregnancy if the expected benefit to mother is greater than any possible risk to fetus. As salbutamol is probably found in breast milk, its use in nursing mother is not recommended unless the expected benefit outweighs any potential risk.

-Before you start to use it

-Use with caution if you have acute severe asthma.

-Taking other medicines

It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to you doctor or pharmacist if you are on the following:-

- Xanthine derivatives
- Steroids
- Non selective beta-blockers such as propranolol or water tablets (diuretics), used to treat high blood pressure or heart condition.

How to use SALMODIL -How much to use

Children: Below 6 year-old: 1.25 to 2.5 ml, 3 to 4 times daily

Older children: 2.5 to 5 ml, 3 to 4 times daily Or as directed by physician.

-How long to use it

Do not stop taking this medicine even when you feel better, unless being advised by your doctor.

-If you forget to use it

If you miss a dose of SALMODIL, take it as soon as possible. However, if its due for the next dose, skip the missed dose and continue with your regular dosing schedule. Do not double up the doses.

-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. Hypokalaemia (deficiency of potassium in the blood stream) may occur following over dosage with salbutamol.

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 SALMODIL.
- 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 SALMODIL to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

It either the usual relief with salbutamol is diminished, or the usual duration of action reduced, you should not increase the dose or its frequency of medicine, but should seek medical advice.

Side effects

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

- Some of the side effects are listed below:
 - Tachycardia (increase heart rate)
 - Palpitation (strong pounding of heart beat)
 - Precordial pain (chest pain)
 - Potentially serious hypokalaemia may result from beta-2 agonist therapy.
 - Nervousness
 - Tremors in few people
 - Nausea
 - 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 <u>npra.moh.gov.my</u> (Public \rightarrow Reporting Medicine Problem/ Side Effect/ AEFI/ Vaccine Safety). Date of revision 25/09/2017

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Storage and Disposal of SALMODIL SYRUP

- <u>Storage</u>

Store in dry place below 30 °C.

- 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 help to protect the environment.

Product Description

- What it looks like

Clear, pink colored syrup having a sweet and slightly bitter taste, with cooling effect.

- <u>Ingredients</u>

- Active ingredient(s)

Salbutamol Sulphate, Bromhexine Hydrochloride

- Inactive ingredients

Sugar, Sodium Benzoate, Sorbitol Solution, Hydrochloric Acid, Propylene Glycol, Carmoisine, Cherry Sweet, Menthol and Purified Water.

<u>-MAL number(s):</u> MAL19871056AZ

Manufacturer

FDC Limited At: B-8 M.I.D.C. Waluj Dist. Aurangabad 431 136 India.

Product Registration Holder

Unimed Sdn. Bhd. No.53 Jalan Tembaga SD 5/2B, Bandar Sri Damansara, 52200 Kuala Lumpur.