

SALMODEX SYRUP

Salbutamol (2.41mg of Salbutamol Sulphate equivalent to 2mg Salbutamol)/Bromhexine Hydrochloride (2mg/4mg per 5ml)

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What SALMODEX is used for

SALMODEX is a bronchodilator (helps open the airways in the lungs) with mucolytic expectorant (to breakdown mucus).

How SALMODEX 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 SALMODEX

-When you must not use it

Tell your doctor before using SALMODEX 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 heart disease.
- 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. SALMODEX 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

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SALMODEX may interfere with each other. They may be affected by SALMODEX or may affect how well it works.

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 SALMODEX

-How much to use

Always use SALMODEX exactly as your doctor has prescribed. You should check with your doctor or pharmacist if in doubt.

The usual dose:

Adults: 5ml, 3 to 4 times a day

Children below 6 years: 1.25 to 2.5 ml, 3 to 4 times a day.

Older children: 2.5 to 5ml, 3 to 4 times a day.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking SALMODEX as your doctor recommended. If symptoms persist, consult your doctor.

-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.

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

While you are using SALMODEX

Things you must do

- Inform your doctor or pharmacist is symptoms persist after taking this medication.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking SALMODEX
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor.
- Do not give SALMODEX 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, SALMODEX can cause side effects, although not everybody gets them.

If symptoms persist, do not take the medicine and refer to the doctor.

SALMODEX may cause severe allergy and serious skin reactions. Stop using SALMODEX and seek medical assistance immediately if you experience any of the following symptoms:

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- 1) severe allergy: breathing difficulties, light headedness, skin swellings or rash.
- 2) severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- 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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my

[Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of SALMODEX

Storage

Store below 30°C. Protect from light. Keep medicine 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 help to protect the environment.

Product description

-What it looks like

Light pink liquid with cherry flavour.

Mode of administration

Oral

Dosage Form

Oral Solution (Liquid)

Packaging

a) 60ml light pink liquid with cherry flavour filled in 60ml amber PET bottle with white HDPE screw cap. A measuring cup is put on top of the capped

bottle. The filled bottle is packed in a pre-printed carton.

b) 100ml light pink liquid with cherry flavour filled in 100ml amber PET bottle with white HDPE screw cap. A measuring cup is put on top of the capped bottle. The filled bottle is packed in a pre-printed carton.

-Ingredients

-Active ingredient

Salbutamol (2.41mg of Salbutamol Sulphate equivalent to 2mg Salbutamol), Bromhexine Hydrochloride

-Inactive ingredients

Levomenthol, Sodium Benzoate, Sodium Citrate, Citric Acid Anhydrous, Saccharin Sodium, Sucralose, Propylene Glycol, Hydroxy Propyl Methyl Cellulose (HPMC), Cherry Flavour, Carmoisine colour and Purified water

-MAL number

Manufacturer and Product

Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd.

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14/05/2020

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