

SALTOLINE SYRUP

Salbutamol Sulphate (2mg/5ml)

What is in this leaflet

1. What SALTOLINE SYRUP is used for
2. How SALTOLINE SYRUP works
3. Before you use SALTOLINE SYRUP
4. How to use SALTOLINE SYRUP
5. While you are using it
6. Side effects
7. Storage and Disposal of SALTOLINE SYRUP
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What SALTOLINE SYRUP is used for

It is used in the relief of asthma, chronic bronchitis (inflammation of the airways that carry air to your lungs), emphysema (damages the air sacs (alveoli) in your lungs) and other bronchopulmonary disorders involving bronchospasm (constriction of the airways).

How SALTOLINE SYRUP works

Salbutamol main action is by relaxing the muscle of the airways of the lungs, and relieve chest tightness, wheezing and cough.

Before you use SALTOLINE SYRUP

- When you must not use it

Do not use SALTOLINE SYRUP if you have:

- High blood pressure
- Myocardial insufficiency (inability of the heart to perform its function)
- Overactive thyroid

Pregnancy and lactation

Risk and benefit should be considered when used during pregnancy. Safe use of the medicine in pregnant women has not been established. It is not known whether Salbutamol is distributed into milk. Therefore a decision should be made whether to discontinue nursing or Salbutamol, taking into account the importance of the medicine to the women.

Ask your doctor or pharmacist for advice before taking SALTOLINE SYRUP if you are pregnant, trying to get pregnant or think you may be pregnant or if you are breastfeeding.

- Before you start to use it

Safety and efficacy of Salbutamol oral solution has not been established in children younger than 2 years of age.

- Taking other medicines

Tocolysis: Serious adverse reactions including death have been reported after intake of Salbutamol by women in labor. In the mother, these include increased heart rate, transient high blood sugar, low blood potassium level, irregular heartbeat, excess fluid in the lungs and reduced blood flow to the heart.

Increase fetal heart rate and newborn low blood sugar may occur as a result of maternal intake.

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.

Salbutamol should not be taken with non-selective beta-adrenoceptor blocking medicines such as Propranolol or Oxprenolol (used for high blood pressure).

How to use SALTOLINE SYRUP

- How much to use

Adults: Oral, 1 to 3 teaspoonfuls (5 - 15 ml) 3-4 times a day initially, the dosage being increased as needed and tolerated up to a maximum of 4 teaspoonfuls (20 ml) 4 times a day.

Children:

Less than 2 years: Dosage has not been established.

2-6 years: 100 mcg/kg body weight, 3 times a day initially. The dosage being increased as needed and tolerated up to 200 mcg/kg body weight not to exceed 4 mg 3 times a day.

6-14 years: 1 teaspoonful (5 ml) 3-4 times a day initially, the dosage being increased as needed and tolerated up to a maximum of 12 teaspoonfuls (60 ml)/day in divided doses.

More than 14 years: Usual adult dose.

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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking SALTOLINE SYRUP 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.

Taking too much of this medication may cause muscle tremors, flushing, agitation, palpitations (pounding of heartbeat), sinus tachycardia (rapid rate heartbeat) and hypokalemia (low potassium level in bloodstream).

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 SALTOLINE SYRUP.

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

Driving and using machines

Be careful when driving or using machines until you know how this medicine affects you.

Side effects

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

Palpitation, tachycardia and muscle tremors may occur. Peripheral blood vessel dilation, tremor, nervousness, nausea, spinning sensation, central stimulation, hyperactivity, excitement, irritable behaviour, insomnia (sleeping difficulty), nose bleed, weakness, dizziness, unusual taste, heartburn, drowsiness, difficulty in urination, cough and drying irritation of the mouth and throat, anorexia (eating disorder), emotional lability, pallor, fatigue, conjunctivitis (redness and inflammation of the thin layer of tissue that covers the front of the eye), muscle cramps and headaches.

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 Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of SALTOLINE SYRUP

- Storage

Keep out of the reach and sight of children.

Keep container tightly closed

Store in dry place below 25°C

Protect from light

Shake well before use

- 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

Red colour syrup with strawberry flavour

- Ingredients

- Active ingredient
Salbutamol (as Salbutamol Sulphate)

- Inactive ingredients

Sugar, Liquid Glucose, Methyl Paraben, Propyl Paraben, Strawberry Flavour, Raspberry Red, Deionised Water

- MAL number:

MAL19910172AZ

Manufacturer and Product

Registration Holder

Dynapharm (M) Sdn. Bhd.
2497, Mk 1, Lorong Perusahaan Baru 5,
Kawasan Perusahaan Perai 3, 13600
Perai, Pulau Pinang, Malaysia

Date of revision

16/03/2017

Serial Number:

BPFK(R4/1)140317/00030