PHARMANIAGA SALBUTAMOL TABLET

Salbutamol (2mg, 4mg)

What is in this leaflet

- 1. What Pharmaniaga Salbutamol Tablet is used for
- 2. How Pharmaniaga Salbutamol Tablet works
- 3. Before you take Pharmaniaga Salbutamol Tablet.
- 4. How to take Pharmaniaga Salbutamol Tablet.
- 5. While you are using Pharmaniaga Salbutamol Tablet
- 6. Side effects
- 7. Storage and disposal of Pharmaniaga Salbutamol Tablet
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

What Pharmaniaga Salbutamol Tablet is used for

It is used help relieve of constriction of the airways in following conditions:

- asthma
- chronic inflammation of the airways that carry air to your lungs
- damages of the air sacs in your lungs

How Pharmaniaga Salbutamol Tablet works

Pharmaniaga Salbutamol Tablet belongs to a group of medicines called bronchodilators. It helps the airways in the lungs to stay open. This makes it easier for air to get in and out.

Before you take Pharmaniaga Tablet

- When you must not to use it

Do not take Pharmaniaga Salbutamol Tablet if you are:

- allergic to any medicine containing salbutamol or to any of the ingredients found in this medicine as listed at the end of this leaflet.
- having threatened abortion during the first or second trimesters.

- Before you start to take it

Tell your doctor or pharmacist if:

 You have allergies to any other medicines, foods, preservatives or dyes.

- You are taking beta-blocking medicines such as propranolol, used to treat high blood pressure or a heart condition.
- You have heart or thyroid problem.
- You are pregnant, plan to become pregnant or are breast-feeding. Unnecessary use of medicines during the first trimester of pregnancy is undesirable.

Your doctor or pharmacist will discuss the risks and benefits involved with the use of Pharmaniaga Salbutamol Tablet if you have any of the above conditions.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any prescribed medicines or any other medicines including herbal medicines and supplements which you obtained from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking:

 beta-blocking medicines such as propranolol

How to use Pharmaniaga Salbutamol Tablet

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label of your medicine, ask your doctor or pharmacist.

- How much to use

Children:

2-6 years: 1-2 mg three or four times daily.

6-12 years: 2 mg three or four times daily.

Over 12 years: 2 mg or 4 mg three or four times daily.

Adults:

The usual effective dose is 2-4 mg three to four times a day depending on the severity of your condition.

The doctor may increase the dose to 8mg per dose if adequate widening the airways is not obtained.

Elderly or individuals' sensitive to salbutamol or other similar products:

Starting dose of 2mg three to four times a day.

- When to use it

Take Pharmaniaga Salbutamol Tablet as directed by your doctor or pharmacist. It can be taken before or after food.

- How long to use it

Continue taking your medicine for as long as your doctor tells you. It is important to keep taking your medicine even if you feel better.

- If you forget to use it

If you miss a dose or forget to take your medicine, take it as soon as you can. However, if it is almost time for your next dose, wait until the usual time to take your medicine and skip the missed dose. Do not double your dose or take extra medicine to make up for a missed dose.

- If you use too much (overdose)

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 there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Pharmaniaga Salbutamol Tablet

- Things you must do

If you or your child who is taking Pharmaniaga Salbutamol Tablet is still not well after taking the medicine, please go back and see your doctor.

- Things you must not do

Do not take Pharmaniaga Salbutamol Tablet to treat any other complaints unless your doctor tells you to.

Do not give Pharmaniaga Salbutamol Tablet to anyone else even if they have the same condition as you.

PHARMANIAGA SALBUTAMOL TABLET

Salbutamol (2mg, 4mg)

Do not take more than the recommended dose unless your doctor tells you to.

- Things to be careful of

Be careful when driving or operating any machinery until you know how Pharmaniaga Salbutamol Tablet affects you.

Side effects

Tell your doctor or pharmacist if you do not feel well while you are taking Pharmaniaga Salbutamol Tablet. This medicine helps most people, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Stop taking Pharmaniaga Salbutamol Tablet and immediately see a doctor if you experience

• an allergic reaction such as swelling of the face, lips, throat or tongue, red raised patches with severe itching or difficulty in breathing

Serious adverse reactions including death have been reported after given terbutaline/ salbutamol to women in labour. In the mother, these include increased heart rate, transient high blood glucose, low blood potassium level, irregular heartbeat, fluid accumulation in the lungs and blood flow to your heart is reduced, preventing it from receiving enough oxygen. Increase fetal and neonatal low glucose level may occur as a result of maternal consumption.

The less serious side effects which may occur with Pharmaniaga Salbutamol Tablet are:

- · Tremors of the hands
- · Headache

This is not a complete list of side effects. The side-effects are caused by the action of salbutamol in your body and usually go away with time. However, if any of them are still bothering you after some time, you should inform your doctor.

Inform your doctor if you notice anything else that is making you feel unwell.

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 Pharmaniaga Salbutamol Tablet

- Storage

Keep the medicines in a cool dry place where the temperature stays below 25°C. Protect from light. Keep container tightly closed.

Do not store it or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car especially on hot days.

Do not use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month.

Keep it where children cannot reach

- 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

Pharmaniaga Salbutamol Tablet 2mg:

Pink, round, biconvex tablet, 7mm in diameter with Pharmaniaga icon on one side and scoreline on the other.

Pharmaniaga Salbutamol Tablet 4mg:

Pink, round, biconvex tablet, 8mm in diameter with Pharmaniaga icon on one side and scoreline on the other.

- Ingredients:

Pharmaniaga Salbutamol Tablet 2mg:

- Active ingredient(s): Salbutamol Sulphate 2mg
- Inactive ingredient(s):

Cornstarch, Magnesium Stearate, Purified Water, Carmoisine Lake, Povidone and Lactose

Pharmaniaga Salbutamol Tablet 4mg:

-Active ingredient(s):-Salbutamol Sulphate 4mg

-Inactive ingredient(s):-Cornstarch, Magnesium Stearate, Purified Water, Lactose Monohydrate, Carmoisine Lake and Povidone

-MAL Number(s):-

Pharmaniaga Salbutamol Tablet 2mg: MAL19870736AZ

Pharmaniaga Salbutamol Tablet 4mg: MAL19870743AZ

1011 121 70 70 7 131 11

Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D),

11A, Jalan P/1,

Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan,

Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing Berhad (60016-D),

11A, Jalan P/1,

Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan,

Malaysia.

Date of revision:

06/04/2018

Serial Number:

NPRA(R4/1)080318/00063