

VENTOLIN[®] TABLET

Salbutamol sulphate (2 mg, 4 mg)

What is in this leaflet

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

What VENTOLIN is used for

VENTOLIN is used in:

- Bronchial asthma
- Chronic bronchitis (inflammation of the airways that carry air to your lungs)
- Emphysema (damages to the air sacs (alveoli) in your lungs)

How VENTOLIN works

VENTOLIN tablets contain salbutamol which belongs to a group of medicines called selective beta-2-adrenoceptor agonists, which can be used to relax the muscles of the airways.

Before you use VENTOLIN

- When you must not use it

Do not take VENTOLIN tablets and tell your doctor if you:

- are allergic (hypersensitive) to salbutamol or any other ingredients in VENTOLIN tablets
- are suspected to have uncomplicated premature labour or threatened abortion

- Before you start to use it

Check with your doctor or pharmacist before taking VENTOLIN tablets if you have:

- an overactive thyroid gland (thyrotoxicosis)
- diabetes

- hypoxia (deficiency in the amount of oxygen reaching the tissues)
- severe heart disease, (such as ischaemic heart disease, irregular heart rhythm, severe heart failure)

Tell your doctor if you experience symptoms such as chest pain, dyspnoea (shortness of breath) or other symptoms of worsening heart disease.

If you are pregnant, planning to become pregnant or are breast-feeding tell your doctor or pharmacist before taking this medicine.

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a sugar called lactose.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- beta-blockers such as propranolol
- xanthine derivatives
- steroids
- diuretics

How to use VENTOLIN

- How much to use

Adults:

Usual dose is 4 mg three or four times a day. Your doctor may increase this gradually up to a maximum of 8 mg three or four times a day.

Some people may be treated successfully with 2mg three or four times a day.

If you are an elderly or known to be sensitive to this product or similar products:

Initially 2mg three or four times a day should be given.

Children 2-6 years:

1-2mg three or four times a day. If a dose of 1 mg is required, the use of salbutamol syrup should be considered.

Children 6-12 years:

2mg three or four times a day.

Children over 12 years:

2-4mg three or four times a day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Always take VENTOLIN tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

- If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

- If you use too much (overdose)

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately.

Symptoms of an overdose include:

- low levels of potassium in the blood which may cause muscle twitching or weakness and an irregular heartbeat.

- Lactic acidosis (buildup of lactic acid in the body)
- Nausea, vomiting and high blood sugar have been reported, predominantly in children

While you are using it

- Things you must do

Swallow the tablets with water.

If you notice the tablets are not working as well as before, contact your doctor for advice.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacist treating you that you are taking VENTOLIN.

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

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

Increasing use of this medicine to control symptoms indicates deterioration of asthma control. Your doctor may monitor you more closely by carrying out certain tests.

Side Effects

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

Tell your doctor if you notice any of the following effects, they get worse or if you notice any not listed:

- an allergic reaction (hypersensitivity): swelling of the face, lips, throat or tongue, pale or red irregular raised patches with severe itching (hives), difficulty breathing, low blood pressure, collapse
- low blood potassium: muscle twitching or weakness, an irregular heartbeat
- other: headaches, increased blood sugar levels, slight shaking, widening of blood vessels, an irregular heartbeat, muscle spasm. An increase in the amount of acid in the body (ketoacidosis) may occur in diabetics.

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 portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of VENTOLIN

- Storage

Keep out of reach and sight of children.

Store below 25°C in a dry place
Do not use VENTOLIN tablets after the expiry date stated on the label/carton. The expiry date refers to the last day of that month.

- 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

VENTOLIN tablets 2 mg are white, round, flat tablets with bevelled edges and engraved with GX/CN3.

VENTOLIN tablets 4 mg are white, round, flat tablets with bevelled edges and engraved with GX/CN5.

Ventolin tablets are available in securitainers of 100s.

- Ingredients

- Active ingredient

2mg or 4mg of salbutamol, as sulphate

- Inactive ingredient(s)

Lactose monohydrate, maize starch, pregelatinised starch, magnesium stearate

- MAL number

VENTOLIN Tablet 2mg

- MAL19961269ACZ

VENTOLIN Tablet 4mg

- MAL19962831ACZ

Manufacturer

Aspen Bad Oldesloe GMBH
Industriestrasse 32-36, 23843,
Bad Oldesloe, Germany

Product Registration Holder

GlaxoSmithKline Pharmaceutical
Sdn. Bhd.

Level 6, Quill 9,
112 Jalan Semangat,
46300 Petaling Jaya,
Selangor, Malaysia

Date of Revision

15 December 2015

BPFK(R4/1)181115/00438