BUTAVENT RESPIRATOR SOLUTION

Salbutamol Sulphate (5mg/ml)

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What BUTAVENT RESPIRATOR SOLUTION is used for

Butavent Respirator Solution helps you breathe more easily. The medicine in your Butavent Respirator Solution gives relief from your chest symptoms, it is often called a 'reliever'.

Butavent Respirator Solution used for the treatments of acute severe asthma (status asthmaticus) and for routine management of chronic bronchospasm (sudden constriction of the muscles in the walls of the airways) unresponsive to conventional therapy.

There are other types of medicines that prevent wheezing or chest tightness. These medicines are called 'preventers' and must be used every day. Your doctor may tell you to use a 'preventer' in addition to your Butavent Respirator Solution.

How BUTAVENT RESPIRATOR SOLUTION works

Butavent Respirator Solution belongs to a group of medicines called bronchodilators. Butavent Respirator Solution works by opening up the airways tubes in your lungs when your chest is tight or when you are wheezing.

Your doctor may have prescribed Butavent Respirator Solution for another reason. Ask your doctor if you have any questions about why Butavent Respirator Solution has been prescribed for you.

Before you use BUTAVENT RESPIRATOR SOLUTION

When you must not use it

Do not take Butavent Respirator Solution if you are allergic to salbutamol or any of the Butavent Respirator Solution ingredients listed at the end of this leaflet. If you have an allergic reaction, you may get a skin rash, or experience difficulty in breathing or faintness.

Do not use Butavent Respirator Solution if you are pregnant or breastfeeding unless you and your doctor or pharmacist has discussed the risks and benefits involved.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

 Any other substances, such as foods, preservatives or dyes.

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Butavent Respirator Solution is not recommended in pregnancy or breastfeeding.

Tell your doctor if you:

- have high blood pressure.
- have high thyroid level.
- have a heart condition.
- have a liver condition.
- have diabetes.
- have kidney impairment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Concurrent use of salbutamol with diuretics, xanthines or high doses of corticosteroids may increase the risk of hypokalaemia (low concentration of potassium in the blood). The antihypertensive effects of diuretics may be reduced when these medications are used with salbutamol.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Butavent Respirator Solution.

How to use BUTAVENT RESPIRATOR SOLUTION

Butavent Respirator Solution must only be used by inhalation from a nebuliser, and must not be injected or swallowed. The nebuliser produces a fine mist which you breathe in through a face mask or a mouthpiece.

Make sure that you know how to use it properly. If you have problems ask your doctor, nurse or pharmacist.

- Do not let the Butavent Respirator Solution, or the mist produced by the nebuliser, get into your eyes.
- Use your nebuliser in a wellventilated room as some of the mist will be released into the

air and may be breathed in by others.

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 pack, ask your doctor or pharmacist for help.

How much to use

Adults and children aged 12 years and above - 0.5mL of Butavent Respirator Solution administered three to four times daily by nebulization. Dilute the 0.5mL of the 0.5% inhalation solution with 2.5mL of sterile normal saline solution.

Children under 12 years of age – 0.5mL of Butavent Respirator Solution administered once daily by nebulization. Dilute the 0.5mL of the 2.5mg Salbutamol into 2.0 to 2.5mL using sterile normal saline solution as diluent.

How to use your Butavent Respirator Solution

- Prepare the nebuliser for filling.
- Measure out the right quantity of Butavent Respirator Solution and put it in the nebuliser bowl.
- Add the right amount of sterile normal saline solution
- Put the top on the nebuliser bowl and shake it gently to mix the contents.
- Assemble the nebuliser and use it as directed.
- After use throw away any solution remaining in the nebuliser bowl. Clean your nebuliser in the recommended way.

When to use it

It does not matter if you take Butavent Respirator Solution before or after food. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to use it

Your doctor will decide how often and for how long you have to take Butavent Respirator Solution.

Do not stop taking Butavent Respirator Solution, or change the dose without first checking with your doctor.

If you forget to use it

If you forget to take a dose, take it as soon as you remember it and if it is time for the next dose, skip the missed dose.

Do not take a double dose of Butavent Respirator Solution to make up for the dose that you missed.

If you use too much (Overdose)

If you take more than you should, talk to a doctor as soon as possible. The following effects may happen:

- your heart beating faster than usual
- you feel shaky

These effects usually wear off in a few hours.

While you are using it

Things you must do

You should only take the dose of Butavent Respirator Solution that is directed by the doctor or pharmacist.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

If you forget a dose, do not worry. Just take the next dose at the normal time.

If your Butavent Respirator Soltuion does not help your breathing as much as usual, tell your doctor as soon as possible.

These may be signs that your chest condition is getting worse.

If your Butavent Respirator Solution is not having the same effect as before, your doctor may decide to prescribe another medicine, for you to use. This medicine is only one part of a general plan to help you manage your asthma or other chest condition.

Go to your doctor regularly for a checkup.

Tell your doctor if you are pregnant or breast-feeding. Your doctor will tell you if you should take your medicine. It is important that asthma is managed well during pregnancy and you should not stop your medicine without asking your doctor.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Butavent Respirator Solution to treat any other complaints unless your doctor says to.

Things to be careful of

Butavent Respirator Solution does not cause drowsiness in most people.

However, you should not drive or carry out skilled tasks, such as using machinery, until you are certain that you are unaffected in this way.

Make sure you know how you react to Butavent Respirator Solution before you drive a car, operate machinery, or do anything else that could be dangerous if you are feeling drowsy. If this occurs do not drive.

Be careful when drinking alcohol while taking Butavent Respirator Solution. Your doctor may suggest you avoid alcohol while you are being treated with Butavent Respirator Solution.

Side Effects

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Butavent Respirator Solution, even if the problem is not listed below.

Like other medicines, Butavent Respirator Solution can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side effects are:

- headache
- nausea
- shaky or tense feeling
- your heart beats faster than usual
- restlessness

Tell your doctor immediately if you notice any of the following:

- skin rash
- faint or dizzy feeling.
- wheezing, swelling of the lips/mouth, difficulty in breathing or fainting. These could be a symptom of an allergic reaction.
- irregular heart beat.

You should stop taking your Butavent Respirator Solution immediately.

In a few people, the medicine in Butavent Respirator Solution may affect their blood potassium levels. Your doctor may do tests to check this.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side- effects not yet known.

Tell your doctor or pharmacist if you notice any side effects from your medicine, which are not mentioned here.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

You may report any side effect or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5550, or visiting the website portal.bpfk.gov.my (Consumer - Reporting).

Storage and disposal of Butavent Respirator Solution

Storage

Any solution remaining in the bottle once it has been opened should not be used later than 1 month.

Keep Butavent Respirator Solution tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Keep your Butavent Respirator Solution in the pack until it is time to take them. If you take the Butavent Respirator Solution out of the pack, they may not keep well.

Do not store Butavent Respirator Solution or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one- and a half meters above the ground is a good place to store medicines.

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

A clear, colourless solution to pale yellow solution.

Ingredients

Active ingredients

Each ml contains Salbutamol Sulphate BP equivalent to Salbutamol 5.0mg.

Inactive ingredients

- Benzalkonium Chloride
- Dilute Sulphuric Acid
- Water for Injection

<u>MAL Number</u> MAL20012731A

Manufacturer

DUOPHARMA (M) SDN BHD (42491 M)
Lot 2599, Jalan Seruling 59 Kaw 3,
Taman Klang Jaya,
41200 Klang,
Selangor Darul Ehsan.

Product Registration Holder

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