

PHARMANIAGA

TERBUTALINE RESPIRATOR SOLUTION

Terbutaline sulphate (2.5mg/mL)

What is in this leaflet

1. What Pharmaniaga Terbutaline Respirator Solution is used for
2. How Pharmaniaga Terbutaline Respirator Solution works
3. Before you use Pharmaniaga Terbutaline Respirator Solution
4. How to use Pharmaniaga Terbutaline Respirator Solution
5. While you are using it
6. Side effects
7. Storage and disposal of Pharmaniaga Terbutaline Respirator Solution
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Pharmaniaga Terbutaline Respirator Solution is used for

Pharmaniaga Terbutaline Respirator Solution is used for the management of bronchial asthma, chronic bronchitis (inflammation of the airways that carry air to your lungs), emphysema (gradual damage to the air sacs (alveoli) in your lungs) and other lung diseases where bronchospasm (tightening of the airways going into the lungs) is a complicating factor.

How Pharmaniaga Terbutaline Respirator Solution works

Pharmaniaga Terbutaline Respirator Solution belongs to a group of medicines called 'bronchodilators' which help to open up the air passages in your lungs so that you can breathe more easily.

Before you use Pharmaniaga Terbutaline Respirator Solution

-When you must not use it

Do not use Pharmaniaga Terbutaline Respirator Solution:

- If you are allergic (hypersensitive) to terbutaline sulphate.
- If you are allergic to any of the other ingredients of Pharmaniaga Terbutaline Respirator Solution.

Pregnancy and lactation

Do not take Pharmaniaga Terbutaline Respirator Solution if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Pharmaniaga Terbutaline Respirator Solution if you are breast-feeding. Terbutaline is distributed into breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Talk to your doctor if any of the following apply to you:

- If you have diabetes
- If you have an overactive thyroid gland
- If you have a heart condition: such as ischemic heart disease (reduced blood supply to the heart), arrhythmia (irregular heartbeat), angina pectoris (chest pain) or a faster than normal heart rate
- If you have high blood pressure
- If you have closed-angle glaucoma (when the iris is pushed forward or backward causing a blockage of drainage angle of the eye)

-Taking other medicines

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

Tell your doctor if you are taking any of the following as they may interact with your medicine:

- Alpha and beta-blocking drugs
- Aminophylline or other Xanthines
- Antihypertensives
- Corticosteroids
- Cyclopropane, halothane or halogenated anaesthetics (may induce ventricular fibrillation)
- Monoamine oxidase treatment or within 14 days of termination (concurrent use may potentiate

the action of terbutaline in the vascular system)

How to use Pharmaniaga Terbutaline Respirator Solution

-How much to use

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.

Pharmaniaga Terbutaline Respirator Solution 2.5mg is ready for use without dilution. Dosage should be individualized.

Body weight > 20kg :
5mg (2ml) is inhaled up to 4 times in a 24 hours period

Body weight < 20kg :
2.5mg(1ml) is inhaled up to 4 times in a 24 hours period

If the entire dose is not inhaled at one occasion it may remain in the nebulizer for up to 24 hours.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking Pharmaniaga Terbutaline Respirator Solution 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.

Excessive adrenergic-receptor stimulation may augment the signs and symptoms listed under **Side effects** and may be accompanied by other adrenergic effects.

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 Pharmaniaga Terbutaline Respirator Solution.

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.

Do not give Pharmaniaga Terbutaline Respirator Solution to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Excessive administration to the nasal mucosa may produce rebound congestion and rhinorrhoea (runny nose). If you are unsure, talk to your doctor.

Side effects

Like all medicines, Pharmaniaga Terbutaline Respirator Solution can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your

doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported. Tell your doctor if any of these side effects become troublesome:

- Trembling or shaking
- Restlessness
- Anxiety
- Insomnia
- Confusion
- Suppressed appetite
- Nausea (feeling sick) and vomiting
- Palpitation (irregular heartbeat)
- Tachycardia (abnormally rapid heart rate)
- Hypotension (low blood pressure)
- Dizziness
- Fainting

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Pharmaniaga Terbutaline Respirator Solution

-Storage

Keep out of the reach and sight of children. Store below 25 °C.

Do not use after the expiry date which is stated on the carton or label. Keep container tightly closed. Protect from light.

-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

Clear, colourless solution.

-Ingredients

-Active ingredient
Terbutaline Sulphate 2.5mg/ml

-Inactive ingredients:

Sodium chloride, Purified water, Disodium edetate, Hydrochloric acid

-MAL number:

MAL19985984A

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

13/08/2015

Serial number

BPFK(R4/1)150715/00200