

# BEROTEC<sup>®</sup> N METERED DOSE INHALER

Fenoterol hydrobromide (100mcg/puff in 10ml)

## What is in this leaflet

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

## What BEROTEC is used for

BEROTEC is used for the:

- a) treatment of acute asthma attacks
- b) prevention of exercise-induced asthma
- c) treatment of asthma and/or other conditions associated with temporary narrowing of the airways such as chronic obstructive bronchitis. Concomitant anti-inflammatory therapy should be considered for people with asthma and steroid responsive chronic obstructive pulmonary disease (COPD)

## How BEROTEC works

BEROTEC is a bronchodilator (anti-asthmatic agent / beta<sub>2</sub>-agonist). Fenoterol is an active substance that rapidly dilates the constricted airways in shortness of breath associated with asthma and inflammation.

## Before you use BEROTEC

- When you must not use it

- if you are hypersensitive (allergic) to fenoterol or any of the other ingredients of this medicine (listed in *Product description*).
- if you suffer from thickened heart muscle that blocks the blood outflow from the heart or with an increased heart rate.

## Children and adolescents

In children BEROTEC should only be used on medical advice and under the supervision of an adult.

## Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor

or pharmacist for advice before taking this medicine.

## - Before you start use it

Take special care with BEROTEC:

- If you have an overactive thyroid gland
- If you have an uncontrolled diabetes
- If you have a phaeochromocytoma (tumour of the adrenal gland)
- If you have a severe blood vessel disease, suffer from a severe underlying disease of the heart (e.g. recent heart attack, reduced blood supply to the heart, heart rhythm disorder, severe heart failure) and if you develop pains in the chest, shortness of breath or other signs of worsening heart disease. In these cases you should seek medical advice.

This particular applies especially when the maximum recommended dose is used.

**Please note:** If you experience sudden, rapidly deteriorating shortness of breath you must contact a doctor without delay.

In these cases it is recommended to monitor potassium levels in blood.

The use of increasing amounts of beta<sub>2</sub>-agonist containing products like BEROTEC<sup>®</sup> on a regular basis to control symptoms of airway obstruction may suggest declining disease control. In this situation, your therapy plan, and in particular the adequacy of the anti-inflammatory therapy should be reviewed by your doctor to prevent potentially life threatening deterioration of disease control.

It can be dangerous to take quantities substantially in excess of the prescribed dose.

Other bronchodilators with beta<sub>2</sub>-adrenergic active ingredients (as also contained in BEROTEC) or anticholinergic active ingredients should be used only under medical supervision (see also the section "Taking other medicines").

## Note

The use of BEROTEC can lead to positive results in doping control tests.

## - Taking other medicines

Tell your doctor or pharmacist if you are currently taking/using, have recently taken/used or intend to take/use, any other medicines.

BEROTEC can interact with certain other medicines. The following medicines are examples that may enhance the effects of fenoterol:

- Beta-adnergics
- Anti-cholinergics
- Xanthine derivatives (eg. Theophylline)
- Corticosteroids - for asthma
- Diuretics, Beta- blockers - for high blood pressure
- Medicines for mental disorder (Monoamine oxidase inhibitors and anti-depressants)
- Halothane (Anaesthetic)

## How to use BEROTEC

### - How much to use

*Acute asthma episodes:*

1 puff is sufficient for prompt symptom relief in most cases, if breathing has not noticeably improved after 5 minutes, a second dose may be taken, up to a maximum of 8 puffs per day.

If an attack has not been relieved by 2 puffs, further puffs may be required. In this situation, you should consult the doctor or the nearest hospital immediately.

*Prevention of exercise induced asthma:*

1 - 2 puffs prior to exercise, up to a maximum of 8 puffs per day.

*Asthma and other conditions with reversible airways narrowing:*

If repeated dosing is required, 1 - 2 puffs for each administration, up to a maximum of 8 puffs per day.

### - When to use it

Inhale according to the following instructions for use:

Correct use of the inhaler is essential for the success of the therapy.

Depress the valve twice before the apparatus is used for the first time. Before each use the following rules should be observed:

1. Remove protective cap.

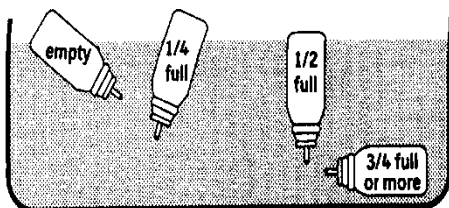


(Fig. 1)

2. Breathe out deeply.
3. Hold the metered aerosol as shown in Fig. 1, and close lips over the mouthpiece. The arrow and the base of the container should be pointing upwards.
4. Breathe in as deeply as possible, pressing the base of the container firmly at the same time, this releases one metered dose. Hold the breath for a few seconds, then remove the mouthpiece and breathe out. If a second inhalation is required, the same action (steps 2-4) should be repeated.
5. Replace the protective cap after use.
6. After not using the metered aerosol for three days the valve has to be actuated once.

The container is not transparent. It is not therefore possible to see when it is empty. The aerosol will deliver **200** doses. When these have all been used the aerosol may still appear to contain a small amount of fluid. The aerosol should, however, be replaced because you may not get the right amount of treatment. The amount of treatment in your aerosol can be checked as follows:

Remove the aerosol from the plastic mouthpiece and put the aerosol into a container of water. The contents of the aerosol can be estimated by observing its position in the water (see Fig. 2)

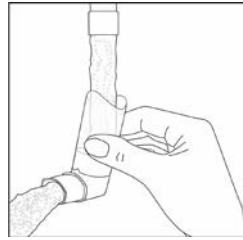


(Fig. 2)

Clean your inhaler at least once a week.

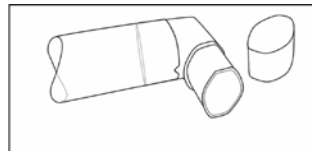
It is important to keep the mouthpiece of your inhaler clean to ensure that medicine does not build up and block the spray.

For cleaning, first take off the dust cap and remove the canister from the inhaler. Rinse warm water through the inhaler until no medication build-up and/or dirt is visible.



(Fig. 3)

After cleaning shake out the inhaler and let it air-dry **without** using any heating system. Once the mouthpiece is dry, replace the canister and the dust cap.



(Fig. 4)

**WARNING:**

The mouthpiece has been specially designed for use with BEROTEC. This mouthpiece should not be used with other metered dose inhalers. The BEROTEC inhaler should be used only with the mouthpiece supplied.

The container is under pressure and should by no account be opened by force or exposed to temperatures above 50°C.

Consult your doctor or pharmacist if you think the effect of BEROTEC is too weak or too strong.

- How long to use it

Continue taking BEROTEC for as long as your doctor recommends.

- If you forget to use it

Do not inhale a double dose to make up for a forgotten inhalation. Inhale the next dose at the next scheduled time.

- If you use too much (overdose)

The symptoms or signs of an overdose correspond to the side effects, but appear very rapidly and may be more intense. Typical signs and symptoms of an overdose:

Faster heartbeat, strong pounding of heart beat, shakiness, high blood pressure, low blood pressure, widening of the pulse pressure, chest pain, irregular heartbeat and flushing. If you have exceeded the prescribed dose you should seek medical help immediately.

**While you are using it**

- Things you must do

Always use BEROTEC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Things you must not do

You may discontinue or prematurely terminate your treatment with BEROTEC only after consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things to be careful of

Driving and using machines

The effects on the ability to drive and use machines have not been investigated. However, you may experience side effects such as dizziness. If this occurs, you should take care during potentially dangerous activities, for example driving a car or using machinery.

BEROTEC contains alcohol

This medicine contains a small amount of alcohol (less than 100 mg per dose).

**Side effects**

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

Immune system disorders

Hypersensitivity

Metabolism and nutrition disorders

Low levels of potassium in the blood

Psychiatric disorders

Agitation, nervousness

Nervous system disorders

Tremor, headache, dizziness

Cardiac disorders

Reduced blood supply to the heart, heart rhythm disorders with altered heart rate, accelerated heart rate, strong pounding of heart beat

Respiratory, thoracic and mediastinal disorders (only applicable to inhalative use)

Unexpected attacks of shortness of breath, cough, throat irritation

Gastrointestinal disorders

Nausea, vomiting

Skin and subcutaneous tissue disorders

Excessive sweating, skin reaction such as rash, itching, hives

Musculoskeletal, connective tissue and bone disorders

Muscle spasm, muscle ache, muscular weakness

Investigations

Reductions and increases in blood pressure

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

**Storage and Disposal of BEROTEC**

- Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the solution container and the 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 you no longer required.

These measures will help to protect the environment.

**Product Description**

- What it looks like

BEROTEC 100mcg metered-dose inhaler contains clear, colourless liquid, free from suspended particles

- Ingredients

- Active ingredient  
Fenoterol hydrobromide

- Inactive ingredients

HFA 134a propellant, Anhydrous citric acid, purified water, 99% ethanol (alcohol),

- MAL number:

MAL20013019AZ

**Manufacturer**

Boehringer Ingelheim Pharma GmbH & Co. KG

Binger Strasse 173

55216 Ingelheim am Rhein

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**Product Registration Holder**

Boehringer Ingelheim (Malaysia) Sdn.Bhd.

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03/08/2018

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