

BIOXITIDETM HFA INHALATION AEROSOL

Salmeterol (as Salmeterol xinafoate)/ Fluticasone propionate (25/125, 25/250 microgram per dose)

What is in this leaflet

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

What BIOXITIDETM is used for
BIOXITIDETM is used to help with breathing problems in people who need regular treatment. Asthma is a long-term condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Chronic obstructive pulmonary disease (COPD) is a long-term, progressively worsening condition affecting the lungs, resulting from chronic bronchitis or emphysema (linings of the air sacs in the lungs damaged beyond repair). Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up mucus. The primary cause of COPD symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

How BIOXITIDETM works

Salmeterol xinafoate is one of a group of medicines called bronchodilators. It relaxes the muscles in the walls of the small air passages in the lungs. This

helps to open the airways and makes it easier for air to get in and out of the lungs. The effects of salmeterol xinafoate last for at least 12 hours. When it is taken regularly it helps the small air passages to remain open.

Fluticasone propionate is one of a group of medicines called corticosteroids which are often referred to simply as steroids. Corticosteroids are used to treat breathing problems because they have an anti-inflammatory action. They reduce the swelling and irritation in the walls of the small air passages in the lungs and so ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

When you take these two ingredients together regularly they will both help to control your breathing difficulties.

Before you use BIOXITIDETM

Some medicines may increase the effects of BIOXITIDETM and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

When you must not use it

Do not use this medicine to treat a sudden attack of breathlessness as it will not help you. You will need a different type of medicine, which you must not confuse with BIOXITIDETM. You should always have your fast-acting 'rescue' medicine available.

Before you start to use it

Consult with your doctor or pharmacist before taking BIOXITIDETM if you are:

- pregnant or likely to become pregnant soon
- breast-feeding
- allergic to salmeterol xinafoate
- allergic to fluticasone propionate

- Being treated for tuberculosis (TB)
- treatment for a thyroid condition
- treatment for high blood pressure or a heart problem
- treatment for diabetes mellitus

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines for asthma or any medicines obtained without a prescription. This is because BIOXITIDETM may not be suitable to be taken with some other medicines.

Tell your doctor if you are taking the following medicines. Before starting to use BIOXITIDETM:

- Beta-blockers (such as atenolol, propranolol, sotalol). Beta-blockers are mostly used for high blood pressure or other heart conditions.
- Antiviral and antifungal medicines (such as ritonavir, ketoconazole and itraconazole).

Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body.

How to use BIOXITIDETM

How much to use

The instructions for using the Inhaler are given on this section of the leaflet. If you have any difficulties or do not understand the instructions, ask your doctor or pharmacist. BIOXITIDETM must only be inhaled through the mouth.

Take your medicine as per your doctors' instructions. The label on it will usually tell you how much to take and how often. If you are not sure ask your doctor or pharmacist.

BIOXITIDETM HFA INHALATION AEROSOL

Salmeterol (as Salmeterol xinafoate)/ Fluticasone propionate (25/125, 25/250 microgram per dose)

The usual dose is:

ASTHMA

Adults and children aged 12 years and above:

Two inhalations of 25 micrograms *Salmeterol* (as *Salmeterol xinafoate*) and 125 *Fluticasone propionate* twice daily

Or

Two inhalations of 25 micrograms *Salmeterol* (as *Salmeterol xinafoate*) and 250 *Fluticasone propionate* twice daily

Children 4 years and older:

The available strength are not suitable for children in this age group. There are no data available for use in children aged less than 4 years.

COPD

For adult patients the recommended dose is two inhalations 25/125 micrograms to 25/250 micrograms *salmeterol* (as *Salmeterol xinafoate*)/ *fluticasone propionate* twice daily.

Special patient groups: There is no need to adjust the dose in elderly patients or in those with renal or hepatic impairment.

Instructions for use

If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of ten days, "test spray" the inhaler. Remove the cap from the mouthpiece; the mouthpiece should be inspected for the presence of foreign objects before each use.



Spray the inhaler 2 times into the air after shaking the device prior to each actuation. Make sure the canister is fully and firmly inserted into the actuator.

Hold the inhaler upright with your thumb on the base. Place either one or two fingers on the top of the canister. Breathe out fully through your mouth expelling as much air from your lungs as possible. Thereafter, place the mouthpiece of the inhaler in your mouth between your teeth. Close your lips around it (do not bite it) tilt your head slightly backwards. Start breathing in slowly through your mouth. As you breathe in steadily and deeply, press down the canister to release one puff.



While holding your breath, you should take off the inhaler from your mouth and should continue holding your breath for 10 seconds or for as long as it is comfortable. Breathe out slowly.



After use, replace the mouthpiece cover.



Cleaning:

Keeping the plastic actuator clean is very important to prevent medicine build up and blockage. The actuator should be washed, shaken to remove excess water and air-dried thoroughly at least once a week. The inhaler may stop spraying if not properly cleaned.

1. Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.
2. Rinse the plastic body and the mouthpiece cover in warm/running water.
3. Dry thoroughly. Avoid excess heat.
4. Replace the canister and the mouthpiece cover correctly.

When to use it

It is very important that you use your BIOXITIDETM every day, as instructed by your doctor. This will help you to keep free of symptoms throughout the day and night.

How long to use it

It is very important that you take your BIOXITIDETM everyday as directed. Keep taking it until your doctor tells you to stop even if you have no symptoms.

If you forget to use it

Take your next dose when it is due. Do not take a double dose to replace the one you forgot.

If you use too much (overdose)

If you accidentally take a larger dose than recommended you may notice that your heart is beating faster than usual and that you feel shaky. Other

BIOXITIDETM HFA INHALATION AEROSOL

Salmeterol (as Salmeterol xinafoate)/ Fluticasone propionate (25/125, 25/250 microgram per dose)

symptoms you may experience include headache, low potassium level (muscle weakness). Tell your doctor as soon as possible if you accidentally take a larger dose than you were told to.

While you are using it

Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Things you must not do

This medicine is for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

Things to be careful of

If you are breathless or wheezing more often than normal, tell your doctor.

Side Effects

Any medicine which contains corticosteroids may have some effect on patients. This is far more common when patients are taking oral corticosteroids. These effects are not usually seen with inhaled corticosteroids, but can occur in patients taking high doses for a long time. It is possible that these patients may experience: loss of bone density, eye problems, slowing of growth in children. Consult your doctor if you are worried about yourself.

Most people taking this medicine find that it causes no problems. As with all medicines, a few people may find that it causes side effects. Some people can be allergic to medicines. If you have any of the following symptoms soon after taking BIOXITIDETM, stop taking this medicine and tell your doctor immediately.

- Sudden wheeziness and chest pain or tightness
- Swelling of eyelids, face, lips, tongue or throat
- Lumpy skin rash or "hives" anywhere on the body

Some people may develop hoarseness, difficulty swallowing or thrush (candidiasis) in their mouth or throat and rarely in their oesophagus. Rinsing with water and spitting it out immediately after each dose may help. Tell your doctor but do not stop treatment unless told to do so.

Also tell your doctor if you have any of the following symptoms: headache, muscle cramps, pains in joints, skin rash or trembling, increase in pulse rate. Some patients may experience increased bruising. There may be an increase in the amount of sugar (glucose) in your blood. If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required. Very rarely the person taking the medicine may feel anxious, have disturbed sleep or notice increase irritability (mainly in children).

Pneumonia (infection of the lung) in COPD patients

(common side effect)

Tell your doctor if you have any of the following while taking BIOXITIDE they could be symptoms of a lung infection:

- Fever or chills;
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties.

If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website portal.bpfk.gov.my (Consumers Reporting)

Storage and Disposal of BIOXITIDETM

Storage

Keep medicine out of reach of children.

Avoid storage in direct sunlight or heat. Store below 30°C.

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

It is a suspension of *Salmeterol xinafoate* & *Fluticasone propionate* which is filled into aluminium can fitted onto a valve. The propellant (Tetrafluoroethane HFA 134a) is then filled into the can through valve. The can fitted with valve & labelled & then again fitted with an actuator and dust cap. This is then packed inside an inner carton with leaflet inside.

Ingredients

Active Ingredients

25 microgram *Salmeterol* (as *Salmeterol xinafoate*) and 125 or 250 microgram *Fluticasone propionate*

Inactive ingredients

Oleic acid, Dehydrated alcohol, Tetrafluoroethane HFA 134a

BIOXITIDE™ HFA INHALATION AEROSOL

Salmeterol (as Salmeterol xinafoate)/ Fluticasone propionate (25/125, 25/250 microgram per dose)

MAL Numbers

Bioxitide™ 25/125 mcg/dose
HFA Inhalation Aerosol
MAL17117031AZ

Bioxitide™ 25/250 mcg/dose
HFA Inhalation Aerosol
MAL17117032AZ

Manufacturer

Biocare Manufacturing Sdn Bhd
Lot 269, Taman Farmaseutikal,
Bandar Baru Seri Iskandar,
32610 Seri Iskandar, Perak.

Product Registration Holder

BioCare Manufacturing Sdn
Bhd
No.67, Jalan Gasing, 46000
Petaling Jaya, Selangor,
Malaysia.

Serial No. : NPRA(R2/1)190709/193

Date of Revision: 22.04.2020