

BREO ELLIPTA

Fluticasone furoate 100 or 200 micrograms and vilanterol (as trifénatate) 25 micrograms per inhalation

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using BREO ELLIPTA.

This leaflet answers some common questions about BREO ELLIPTA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BREO ELLIPTA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What BREO ELLIPTA is used for

BREO ELLIPTA is used to treat asthma and chronic obstructive pulmonary disease (COPD). To use BREO ELLIPTA, you breathe it into your lungs through your mouth using the ELLIPTA inhaler.

Asthma is when the muscles surrounding the smaller airways become tight (bronchoconstriction), swollen and irritated (inflammation). Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

COPD is a long-term condition that slowly gets worse. Symptoms

include shortness of breath, cough, chest discomfort and coughing up mucus. BREO ELLIPTA has been shown to reduce flare-ups of COPD symptoms.

BREO ELLIPTA contains two active ingredients: fluticasone furoate and vilanterol trifénatate.

Fluticasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Corticosteroids are used to reduce inflammation. They reduce the swelling and irritation in the small air passages in the lungs and so ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

Vilanterol trifénatate belongs to a group of medicines called bronchodilators. It relaxes the muscles 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. When it is taken regularly, it helps the small air passages to remain open.

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

BREO ELLIPTA should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack you must use a quick-acting inhaler (such as VENTOLIN).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

BREO ELLIPTA should not be used in children under the age of 12 years.

Before you use BREO ELLIPTA

Bronchodilators similar to vilanterol (one of the ingredients in BREO ELLIPTA) as a class of medicines can very rarely be associated with an increased risk of potentially life-threatening worsening of your asthma. However, not treating your asthma sufficiently can also similarly put you at risk. Your doctor has weighed any risks of you using BREO ELLIPTA against the benefits they expect it will have for you. You can talk to your doctor about the risks and benefits of using this medicine.

When you must not use it

Don't use BREO ELLIPTA

- if you are allergic (hypersensitive) to lactose or milk protein**
- if you are allergic (hypersensitive) to fluticasone furoate, vilanterol or any other ingredients of BREO ELLIPTA (listed at the end of this leaflet).**

If you think either of these applies to you, don't use BREO ELLIPTA until you have checked with your doctor.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin
- BREO ELLIPTA contains lactose.

If you have been diagnosed with an intolerance to some sugars, or to milk protein, talk to your doctor before you use BREO ELLIPTA.

BREO ELLIPTA is not usually recommended for use during pregnancy.

If you are pregnant, if you think you may be pregnant don't use BREO ELLIPTA without asking your doctor.

Your doctor will consider the benefit to you and the risk to your baby of taking BREO ELLIPTA while you are pregnant.

If you are breast-feeding, check with your doctor before you take BREO ELLIPTA.

It is not known whether the ingredients of BREO ELLIPTA can pass into breast milk.

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

BREO ELLIPTA 200/25 is not recommended in asthma patients aged 75 years and older.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Your doctor should give you a personal Action Plan to help manage your asthma or COPD. This plan will include what medicines to take regularly to control your asthma or COPD, as well as what

"reliever" medicines to use when you have sudden attacks of breathlessness or wheezing.

Ask your doctor or pharmacist if you have any questions about your Action Plan.

Talk to your doctor before you use BREO ELLIPTA if you:

- have liver disease, as you may be more likely to have side effects. If you have moderate or severe liver disease, your doctor will limit your dose to the lower strength of BREO ELLIPTA (100/25 micrograms once daily).
- have heart problems or high blood pressure
- if you have ever been told you have diabetes or high blood sugar
- are being or have ever been treated for tuberculosis (TB) or pneumonia
- have eye problems such as glaucoma or cataracts
- have weak bones (osteoporosis)
- have diabetes
- have problems with your thyroid
- have seizures
- have any long-standing or untreated infections or have recently been exposed to chickenpox or measles or been around anyone who has chickenpox or measles
- have any other medical conditions
- if you have a problem with your immune system

Check with your doctor before you use BREO ELLIPTA if you think any of these apply to you.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. This should include all of the medicines that you are using for your asthma or COPD.

Medicines which are similar to BREO ELLIPTA should not be used together as an overdose may result.

Some medicines may affect how BREO ELLIPTA works, or make it more likely that you'll have side effects. These include:

- ketoconazole, to treat fungal infections.
- ritonavir, to treat viral infections
- medicines to treat depression or mood/mental disorders (such as monoamine oxidase inhibitors or tricyclic antidepressants).

A class of medicines known as "beta-blockers" used to treat high blood pressure or a heart condition should be avoided.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use BREO ELLIPTA

Follow all directions given to you by your doctor or pharmacist carefully.

If you do not understand the instructions in the user leaflet, ask your doctor or pharmacist for help.

How much to use

Always use BREO ELLIPTA exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you're not sure.

Asthma

The usual dose of BREO ELLIPTA for asthma is one inhalation 100 micrograms of fluticasone furoate and 25 micrograms of vilanterol once daily at the same time each day.

If you have severe asthma, your doctor may decide that you should use one inhalation of the higher strength BREO ELLIPTA inhaler (200 micrograms fluticasone furoate and 25 micrograms of vilanterol).

Your doctor will assess your asthma at regular intervals to ensure that you are receiving the dose most suitable to the severity of your asthma.

COPD

The dose of BREO ELLIPTA for COPD is one inhalation 100 micrograms of fluticasone furoate and 25 micrograms of vilanterol once daily at the same time each day.

The higher strength of BREO ELLIPTA is not suitable for the treatment of COPD.

How to use the inhaler

The full instructions for using BREO ELLIPTA are given on a leaflet inside the pack.

BREO ELLIPTA is ready to use straight away. No preparation or checks of the inhaler are required.

Do not open BREO ELLIPTA until you are ready to take a dose.

After using BREO ELLIPTA, you may clean the mouthpiece, using a dry tissue, before you close the cover. Do not immerse BREO ELLIPTA in water.

When to use it

Use BREO ELLIPTA regularly.

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

If you feel you are getting breathless or wheezy more often

than normal, or if you are using your quick-acting inhaler more than usual, see your doctor.

How long to use it

Don't stop BREO ELLIPTA without medical advice.

Use BREO ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Don't stop unless your doctor advises you to, even if you feel better.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, then go back to using it as you would normally.

Don't take an extra dose to make up for a missed dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you become wheezy or breathless, or develop any other symptoms of an asthma attack, use your quick-acting inhaler (e.g. VENTOLIN), then seek medical advice.

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

If you take too much (overdose)

In Australia, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much BREO ELLIPTA. Do this even if there are no signs of discomfort or poisoning.

If you accidentally take a larger dose of BREO ELLIPTA than your doctor has instructed, you may notice that your heart is beating faster than usual, you feel shaky or have a headache.

If you have used larger doses than instructed for a long period of time,

it is particularly important that you ask your doctor or pharmacist for advice. This is because larger doses of BREO ELLIPTA may reduce the amount of steroid hormones produced naturally by your body.

While you are using BREO ELLIPTA

Things you must do

Contact your doctor if you experience a change in your vision.

Contact your doctor if you experience increased thirst, frequent urination or unexplained tiredness (signs of high blood sugar).

If you have an Action Plan for your asthma or COPD that you have agreed with your doctor, follow it closely at all times.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BREO ELLIPTA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take BREO ELLIPTA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take any other medicines for your breathing problems

without checking with your doctor.

Things to be careful of

This medicine is not expected to affect your ability to drive a car or operate machinery. It is prudent to be careful with driving or operating machinery until you know how BREO ELLIPTA affects you.

Side effects

Like all medicines, BREO ELLIPTA can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest effective dose of BREO ELLIPTA to control your asthma or COPD.

If your breathing or wheezing gets worse straight after using BREO ELLIPTA, stop using it and get medical help immediately.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Very Common side effects

These may affect more than 1 in 10 people:

- headache
- common cold

Common side effects

These may affect up to 1 in 10 people:

- sore, raised patches in the mouth or throat caused by a fungal infection (candidiasis). Rinsing your mouth out with water immediately after using BREO ELLIPTA may help stop this side effect developing
- infection of the lungs (pneumonia).

You must tell your doctor if

you have any of the following symptoms while taking BREO ELLIPTA: fever, chills, increased sputum production, change in sputum colour, increased cough or increased breathing difficulties.

- inflammation of the lungs (bronchitis)
- infection of the nose sinuses or throat
- flu (influenza)
- pain and irritation in the back of the mouth and throat
- inflammation of the sinuses
- itchy, runny or blocked nose
- cough
- voice disorders
- weakening of the bones, leading to risk of fractures
- stomach pain
- high temperature (fever)
- joint and back pain
- muscle spasms

Uncommon side effects

These may affect up to 1 in 100 people:

- irregular heartbeat
- increase in blood sugar (hyperglycaemia). This may lead to increased thirst, frequent urination or unexplained tiredness.

If you think you are having an allergic reaction to BREO ELLIPTA, stop using this medicine and tell your doctor immediately or go to the accident and emergency department at your nearest hospital. Symptoms of an allergic reaction usually include some or all of the following:

- wheezing
- swelling of the lips/mouth, tongue or throat
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

It is possible that some people particularly those taking higher doses of BREO ELLIPTA for a long time, may rarely suffer from the following side effects:

- Rounded face
- Loss of bone density
- Eye problems (e.g. cataract, glaucoma)
- Slowing of growth in children. It is unclear what, if any, difference this makes to a child's final height
- Immediate breathing difficulties and wheezing.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

After using BREO ELLIPTA

Storage

Do not use BREO ELLIPTA after the expiry date shown on the pack.

Store in the original package container in order to protect from moisture and do not open the foil lid until ready to inhale for the first time.

Safely throw away BREO ELLIPTA one month after you open the foil tray or when the counter reads "0", whichever comes first. Write the date the inhaler should be discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

Keep your inhaler in cool dry place where the temperature stays below 30°C.

If you store in a refrigerator allow the inhaler to return to room temperature for at least an hour before use.

Do not store BREO ELLIPTA or any other medicine in the bathroom or near a sink. Do not

leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

BREO ELLIPTA is inhaled through the mouth using the ELLIPTA device. The active substances are in separate blisters in powder form inside the device. There are either 14 or 30 blisters on each strip, and so each device contains either 14 or 30 doses depending on which pack size you have been given.

The ELLIPTA device itself is a plastic inhaler with a light grey body, a pale blue mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a desiccant sachet, to reduce the moisture in the packaging. Once you have opened the lid of the tray, throw the desiccant away - do not open, eat or inhale it.

Ingredients

The active ingredients in BREO ELLIPTA are fluticasone furoate and vilanterol (as trifénatate).

Each dose contains 100 or 200 micrograms of the active ingredient fluticasone furoate. Each dose also contains 25 micrograms of the active ingredient vilanterol. The amount depends on which strength

of BREO ELLIPTA you have been given.

BREO ELLIPTA also contains the inactive ingredients:

- lactose monohydrate
- magnesium stearate

Supplier

Your BREO ELLIPTA is supplied by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford Victoria 3067
Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and books, for example in public libraries.

This leaflet was prepared on 11 Sep 2018.

The information provided applies only to: BREO ELLIPTA.

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