

Package leaflet: Information for the user

Trimbow

88 micrograms/5 micrograms/9 micrograms inhalation powder

beclometasone dipropionate/Formoterol fumarate dihydrate/glycopyrronium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trimbow is and what it is used for
2. What you need to know before you use Trimbow
3. How to use Trimbow
4. Possible side effects
5. How to store Trimbow
6. Contents of the pack and other information

1. What Trimbow is and what it is used for

Trimbow is a medicine to help breathing that contains the three active substances:

- beclometasone dipropionate,
- formoterol fumarate dihydrate and
- glycopyrronium.

Beclometasone dipropionate belongs to a group of medicines called corticosteroids which act to reduce the swelling and irritation in your lungs.

Formoterol and glycopyrronium are medicines called long-acting bronchodilators. They act in different ways to relax the muscles in your airways, helping to open the airways wider and allowing you to breathe more easily.

Regular treatment with these three active substances helps to relieve and prevent symptoms such as shortness of breath, wheezing and cough in adult patients with chronic obstructive pulmonary disease (COPD). Trimbow can reduce exacerbations (flare-ups) of COPD symptoms. COPD is a serious long-term disease in which the airways become blocked and air sacs inside the lungs become damaged, leading to difficulty breathing.

2. What you need to know before you use Trimbow

Do not use Trimbow

If you are allergic to beclometasone dipropionate, formoterol fumarate dihydrate and/or glycopyrronium or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Trimbow is used as a maintenance treatment for your obstructive lung disease. Do not use this medicine to treat a sudden attack of breathlessness or wheezing.

If your breathing gets worse

If you develop worsening shortness of breath or wheezing (breathing with a whistling sound), straight after inhaling your medicine, stop using Trimbow inhaler and use your quick-acting “reliever” inhaler straightaway. You should contact your doctor straightaway. Your doctor will assess your symptoms and if necessary may start you on a different treatment.

See also section 4, “Possible side effects”.

If your lung disease gets worse

If your symptoms get worse or are difficult to control (e.g. if you are using a separate “reliever” inhaler more frequently) or if your “reliever” inhaler does not improve your symptoms, see your doctor immediately. Your lung disease may be getting worse and your doctor may need to prescribe different treatment.

Talk to your doctor or pharmacist before using Trimbow:

- if you have any heart problems, such as angina (heart pain, pain in the chest), a recent heart attack (myocardial infarction), heart failure, narrowing of the arteries around your heart (coronary heart disease), disease of your heart valves or any other abnormalities of your heart or if you have a condition known as hypertrophic obstructive cardiomyopathy (also known as HOCM, a condition where the heart muscle is abnormal).
- if you have disorders of your heart rhythm such as irregular heart rate, a fast pulse rate or palpitations or if you have been told that your heart trace (ECG) is abnormal.
- if you have narrowing of the arteries (also known as arteriosclerosis), if you have high blood pressure or if you have an aneurysm (abnormal bulging of the blood vessel wall).
- if you have an overactive thyroid gland.
- if you have low blood levels of potassium (hypokalaemia). The combination of Trimbow with some other lung medicines or medicines such as diuretics (medicines that make the body lose water, to treat heart disease or high blood pressure), can cause a sharp fall in your blood level of potassium. Therefore, your doctor may wish to measure the potassium levels in your blood from time to time.
- if you have any disease of your liver or kidneys.
- if you have diabetes. High doses of formoterol may increase your blood glucose and therefore you may need to have extra blood tests to check your blood sugar when you start using this medicine, and from time to time during treatment.
- if you have a tumour of the adrenal gland (known as a pheochromocytoma).
- if you are due to have an anaesthetic. Depending on the type of anaesthetic, it may be necessary to stop using Trimbow at least 12 hours before the anaesthesia.
- if you are being, or have ever been, treated for tuberculosis (TB) or if you have a chest infection.
- if you have an eye problem called narrow-angle glaucoma.
- if you have difficulty passing urine.
- if you have an infection of the mouth or throat.

If any of the above applies to you, tell your doctor before you use Trimbow.

If you have or have had any medical problems or any allergies or if you are not sure if you can use Trimbow, talk to your doctor or pharmacist before using the inhaler.

If you are already using Trimbow

If you are using Trimbow or high doses of other inhaled corticosteroids over long periods and you come into a situation of stress (e.g. being taken to hospital after an accident, having a serious injury or before an operation) you may need more of this medicine. In such a situation, your doctor may need to increase your dose of corticosteroids to cope with the stress and may prescribe them as tablets or injections. Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

Do not give this medicine to children and adolescents below the age of 18 years.

Other medicines and Trimbow

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines similar to Trimbow used for your lung disease.

Some medicines may increase the effects of Trimbow and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Do not use this medicine with a beta-blocker medicine (used for treating certain heart problems such as angina or for reducing blood pressure) unless your doctor has chosen a beta-blocker that does not affect your breathing. Beta-blockers (including beta-blocker eye-drops) may reduce the effects of formoterol or make it not work at all. On the other hand, using other beta2-agonist medicines (which work in the same way as formoterol) may increase the effects of formoterol.

Using Trimbow together with:

- medicines for treating
 - abnormal heart rhythms (quinidine, disopyramide, procainamide),
 - allergic reactions (antihistamines),
 - symptoms of depression or mental disorders such as monoamine oxidase inhibitors (for example phenelzine and isocarboxazid), tricyclic antidepressants (for example amitriptyline and imipramine), phenothiazinescan cause some changes in the electrocardiogram (ECG, heart trace). They may also increase the risk of disturbances of heart rhythm (ventricular arrhythmias).
- medicines for treating Parkinson’s disease (levodopa), to treat an underactive thyroid gland (levothyroxine), medicines containing oxytocin (which causes uterine contraction) and alcohol can increase the chances of formoterol side effects on the heart.
- monoamine oxidase inhibitors (MAOIs), including medicines with similar properties like furazolidone and procarbazine, used to treat mental disorders, can cause a rise in blood pressure.
- medicines for treating heart disease (digoxin) can cause a fall in your blood potassium level. This may increase the likelihood of abnormal heart rhythms.
- other medicines used to treat obstructive lung disease (theophylline, aminophylline or corticosteroids) and diuretics may also cause a fall in your potassium level.
- some anaesthetics can increase the risk of abnormal heart rhythms.

Pregnancy and breast-feeding

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 using this medicine. You should only use Trimbow during pregnancy if you are advised to do so by your doctor. It is preferable to avoid the use of Trimbow during labour due to the inhibitory effects of formoterol on uterine contractions. You should not use Trimbow during breast-feeding. You and your doctor must make a decision whether to discontinue breast-feeding or to discontinue/abstain from Trimbow therapy taking into account the benefit of breast-feeding for your child and the benefit of therapy for you.

Driving and using machines

Trimbow is unlikely to affect your ability to drive and use machines.

Trimbow contains lactose

Lactose contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use Trimbow

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

The recommended dose is two inhalations in the morning and two inhalations in the evening.

If you feel that the medicine is not very effective, talk to your doctor. If you have been using a different inhaler containing beclometasone dipropionate previously, ask your doctor for advice, as the effective dose of beclometasone dipropionate in Trimbow for the treatment of your obstructive lung disease may be lower than that of some other inhalers.

Route of administration

Trimbow is for inhalation use.

You should inhale the medicine through your mouth and this takes the medicine directly into your lungs.

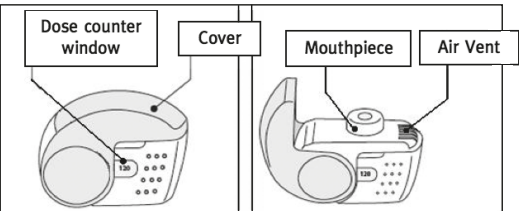
Instructions for use

For information on the contents of the pack, see section 6.

If the pack contents are not the same as described in section 6, return your inhaler to the person who supplied it and get a new one.

- **Do not** remove the inhaler from the pouch if you do not intend to use it immediately.
- Only use your inhaler as indicated.
- Keep the cover closed until you need to take a dose from your inhaler.
- When you are not using your inhaler keep it in a clean and dry place.
- **Do not** attempt to take your inhaler apart for any reason.

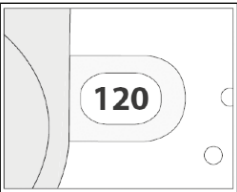
A. Key features of your inhaler



Taking a dose from your inhaler requires three steps: Open, Inhale, Close

B. Before using a new inhaler

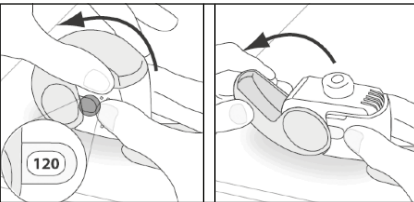
1. **Open the pouch and take out your inhaler.**
 - **Do not** use your inhaler if the pouch is not sealed or it is damaged – return it to the person who supplied it and get a new one.
 - Use the label on the box to write down the date you open the pouch.
2. **Inspect your inhaler.**
 - If your inhaler looks broken or damaged, return it to the person who supplied it and get a new one.
3. **Check the Dose Counter Window. If your inhaler is new you will see “120” in the Dose Counter Window.**
 - **Do not** use a new inhaler if the number shown is less than “120” – return it to the person who supplied it and get a new one.



C. How to use your inhaler

C.1. Open

1. **Hold your inhaler firmly in the upright position.**
2. **Check the number of doses left: any number between “1” and “120” shows that there are doses left.**
 - If the Dose Counter Window shows “0” there are no doses left – dispose of your inhaler and get a new one.
3. **Open the cover fully.**



4. **Before inhaling breathe out as far as is comfortable.**
 - **Do not** breathe out through your inhaler.

C.2. Inhale

Whenever possible, stand or sit in an upright position when inhaling.

1. **Lift your inhaler up, bring it to your mouth and place your lips around the mouthpiece.**
 - **Do not** cover the air vent when holding your inhaler.
 - **Do not** inhale through the air vent.
2. **Take a forceful and deep breath through your mouth.**
 - You may notice a taste when you take your dose.
 - You may hear or feel a click when you take your dose.
 - **Do not** inhale through your nose.
 - **Do not** remove your inhaler from your lips during the inhalation.

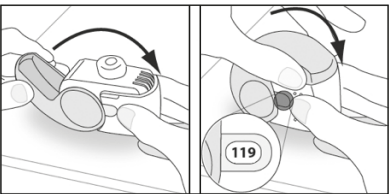


3. **Remove your inhaler from your mouth.**
4. **Hold your breath for 5 to 10 seconds or as long as is comfortable.**
5. **Breathe out slowly.**
 - **Do not** breathe out through your inhaler.

- If you are not sure you are receiving your dose correctly contact your pharmacist or doctor.

C.3. Close

1. **Move your inhaler back to the upright position and close the cover fully.**
2. **Check that the dose counter has gone down by one.**



- If you are not sure the dose counter has gone down by one after inhalation, wait until your next scheduled dose and take this as normal. Do not take an extra dose.

3. **If you need to take another dose, repeat steps C.1 to C.3.**

D. Cleaning

- Normally, it is not necessary to clean your inhaler.
- If necessary, you may clean your inhaler after use with a dry cloth or tissue.
 - **Do not** clean your inhaler with water or other liquids. Keep it dry.

If you use more Trimbow than you should

It is important that you take your dose as advised by your doctor. Do not exceed your prescribed dose without talking to your doctor.

If you use more Trimbow than you should, side effects, as described in section 4, may occur.

Tell your doctor if you have used more Trimbow than you should and if you experience any of these symptoms. Your doctor may wish to carry out some blood tests.

If you forget to use Trimbow

Use it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, but just take the next dose at the correct time. Do not double the dose.

If you stop using Trimbow

It is important to use Trimbow every day. Do not stop using Trimbow or lower the dose, even if you are feeling better or you have no symptoms. If you want to do this, talk to your doctor.

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

4. Possible side effects

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

There is a risk of worsening shortness of breath and wheezing immediately after using Trimbow and this is known as paradoxical bronchospasm (may affect up to 1 in 1,000 people). If this occurs you should stop using Trimbow and use your quick-acting “reliever” inhaler straightaway to treat the shortness of breath and wheezing. You should contact your doctor straightaway.

Tell your doctor immediately

- if you experience any allergic reactions like skin allergies, hives, skin itching, skin rash (may affect up to 1 in 100 people), reddening of the skin, swelling of the skin or mucous membranes especially of the eyes, face, lips and throat (may affect up to 1 in 1,000 people).
- if you experience eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes. These may be signs of an acute attack of narrow-angle glaucoma (may affect up to 1 in 10,000 people).

Tell your doctor if you have any of the following while using Trimbow as they could be symptoms of a lung infection (may affect up to 1 in 10 people):

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties.

Possible side effects are listed below according to their frequency.

Common (may affect up to 1 in 10 people)

- sore throat
- runny or stuffy nose and sneezing
- fungal infections of the mouth. Rinsing your mouth or gargling with water and brushing your teeth immediately after inhalation may help to prevent these side effects
- hoarseness
- headache
- urinary tract infection.

Uncommon (may affect up to 1 in 100 people)

- flu
- inflammation of the sinuses
- itchy, runny or blocked nose
- fungal infections of the throat or of the food pipe (oesophagus)
- fungal infections of the vagina
- restlessness

- trembling
- dizziness
- abnormal or reduced sense of taste
- numbness
- inflammation of the ear
- irregular heart beat
- changes in the electrocardiogram (heart trace)
- unusually fast heart beat and disorders of the heart rhythm
- palpitations (feeling of abnormal beating of the heart)
- reddening of the face
- increased blood flow to some tissues in the body
- asthma attack
- cough and productive cough
- irritation of the throat
- nose bleeds
- redness of the pharynx
- dry mouth
- diarrhoea
- swallowing difficulties
- feeling sick
- upset stomach
- stomach discomfort after meals
- burning sensation of the lips
- tooth decay
- skin rash, hives, skin itching
- inflammation of the mucous membrane of the mouth with or without ulcers
- increased sweating
- muscle cramps and pain in muscles
- pain in arms or legs
- pain in muscles, bones or joints of the chest
- tiredness
- increase of blood pressure
- fall in the level of some constituents of your blood: of certain white blood cells called granulocytes, of potassium or of cortisol
- increase in the level of some constituents of your blood: glucose, C-reactive protein, number of platelets, insulin, free fatty acid or ketones.

- Rare** (may affect up to 1 in 1,000 people)
- fungal infections of the chest
 - decreased appetite
 - sleep disorders (sleeping too little or too long)
 - crushing chest pain
 - sensation of a missed heart beat or of extra heart beats, unusually slow heart beat
 - worsening of asthma
 - leakage of blood from a vessel into the tissues surrounding it
 - decrease of blood pressure
 - weakness
 - pain in the back of the mouth and throat
 - inflammation of the pharynx
 - dry throat
 - painful and frequent urination
 - difficulty and pain when passing urine
 - inflammation of the kidneys.

- Very rare** (may affect up to 1 in 10,000 people)
- low level in the number of certain blood cells called platelets
 - feeling breathless or short of breath
 - swelling of the hands and feet
 - growth retardation in children and adolescents.

- Not known** (frequency cannot be estimated from the available data)
- blurred vision.

Using high-dose inhaled corticosteroids over a long time can cause in very rare cases effects on the body:

- problems with how your adrenal glands work (adrenal suppression)
- decrease in bone mineral density (thinning of the bones)
- clouding of the lens of your eyes (cataract).

Trimbow does not contain a high-dose inhaled corticosteroid, but your doctor may wish to measure the cortisol levels in your blood from time to time.

The following side effects can also occur with high-dose inhaled corticosteroids used over a long time, but the frequency is not known (frequency cannot be estimated from the available data) at present:

- depression
- feeling worried, nervous, over-excited or irritable.

These events are more likely to occur in children.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trimbow

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

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the inhaler in the original package in order to protect from moisture and only remove from the pouch immediately before first use.

After first opening the pouch the medicine should be used within 6 weeks and stored in a dry place. Use the adhesive label on the outer carton to write down the date you open the pouch and stick this label to the bottom of the inhaler.

Do not throw away any medicines via waste-water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Trimbow contains

The active substances are: beclometasone dipropionate, formoterol fumarate dihydrate and glycopyrronium.

Each delivered dose (the dose leaving the mouthpiece) contains 88 micrograms of beclometasone dipropionate, 5 micrograms of formoterol fumarate dihydrate and 9 micrograms of glycopyrronium (as 11 micrograms glycopyrronium bromide).

Each metered dose contains 100 micrograms of beclometasone dipropionate, 6 micrograms of formoterol fumarate dihydrate and 10 micrograms of glycopyrronium (as 12.5 micrograms of glycopyrronium bromide).

The other ingredients are: lactose monohydrate (see section 2) and magnesium stearate.

What Trimbow looks like and contents of the pack

Trimbow is a white to almost white inhalation powder. It is provided in a white plastic inhaler called NEXThaler with a grey mouthpiece cover and a counter for the inhalations. Each inhaler is packed in a sealed protective pouch.

Trimbow is available in packs containing one inhaler, and in multipacks comprising two or three inhalers, providing 120 inhalations each (120, 240 or 360 inhalations). Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chiesi Limited
333 Styal Road
Manchester
M22 5LG
UK

Manufacturer

Chiesi Farmaceutici S.p.A.
Via San Leonardo 96
43122 Parma
Italy

Chiesi SAS
2 rue des Docteurs Alberto et Paolo Chiesi
41260 La Chaussée Saint Victor
France

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