Package leaflet: Information for the user

Trimbow

87 micrograms/5 micrograms/9 micrograms
pressurised inhalation, solution

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

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 obstructive lung disease. Trimbow is used for the regular treatment of
- chronic obstructive pulmonary disease (COPD) in adults
- asthma in adults.

Trimbow can reduce exacerbations (flare-ups) of COPD and asthma 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.

Asthma is a serious, long-term disease where the muscles surrounding the airways become tight (bronchoconstriction) and swollen and irritated (inflammation). Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

You should use Trimbow every day and not only when you have breathing problems or other symptoms of asthma. This will ensure that it controls your asthma properly. Do not use this medicine to relieve a sudden attack of breathlessness or wheezing.

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 phaeochromocytoma).
- 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

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antidepressants (for example amitriptyline and imipramine), phenothiazines
can 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.

- Disulfiram, a medicine used in the treatment of people with alcoholism (drinking problems) or metronidazole, an antibiotic to treat infection in your body can cause side effects (e.g. feeling sick, being sick, stomach pain) due to the small amount of alcohol in Trimbow.

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 ethanol
Trimbow contains 8.856 mg of alcohol (ethanol) in each actuation, which is equivalent to 17.712 mg per dose of two actuations. The amount in two actuations of this medicine is equivalent to less than 1 ml of wine or beer. The small amount of alcohol in this medicine will not have any noticeable effects.

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 puffs in the morning and two puffs in the evening.

Do not use more than your doctor tells you to use.
You should use Trimbow every day, even when your asthma is not troubling you.
Do not use this medicine to relieve a sudden attack of breathlessness or wheezing.

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.

This medicine is contained in a pressurised container in a plastic inhaler with a mouthpiece.

Trimbow is available in three container sizes:
- a container providing 60 puffs
- a container providing 120 puffs
- a container providing 180 puffs.

If you have been prescribed a container providing 60 puffs or 120 puffs
There is a counter on the back of the inhaler, which tells you how many doses are left. Each time you press the pressurised container, a puff of medicine is released and the counter will count down by one. Take care not to drop the inhaler as this may cause the counter to count down.

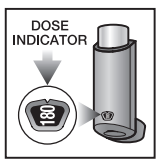
If you have been prescribed a container providing 180 puffs
There is an indicator on the back of the inhaler, which tells you how many doses are left. Each time you press the pressurised container, a puff of medicine is released and the dose indicator rotates by a small amount. The number of puffs remaining is displayed in intervals of 20. Take care not to drop the inhaler as this may cause the dose indicator to count down.

Testing your inhaler
Before using the inhaler for the first time, you should test your inhaler to make sure that it is working properly, as follows.
1. Depending on the container size prescribed to you, check that the dose counter reads 61 or 121 and that the dose indicator reads 180
2. Remove the protective cap from the mouthpiece
3. Hold your inhaler upright with the mouthpiece at the bottom
4. Direct the mouthpiece away from yourself and firmly press the pressurised container to release one puff
5. Check the dose counter or dose indicator. If you are testing your inhaler for the first time, the counter should read:

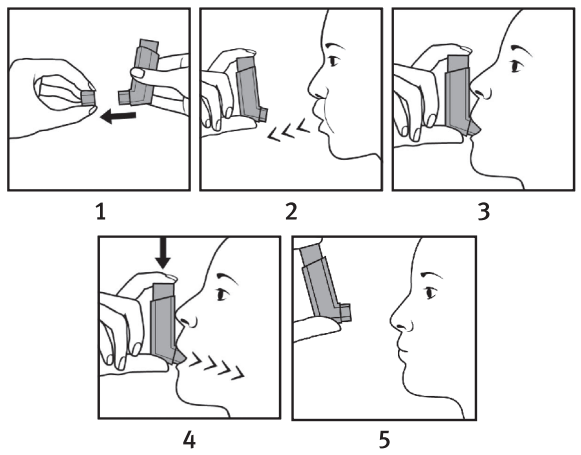
60
- when using the container providing 60 puffs

120
- when using the container providing 120 puffs

180
- when using the container providing 180 puffs



How to use your inhaler
Stand or sit up when inhaling.
IMPORTANT: Do not perform steps 2 to 5 too quickly.



1. Remove the protective cap from the mouthpiece and check that the mouthpiece is clean and free from dust and dirt.
2. Breathe out as slowly and deeply as possible, in order to empty your lungs.
3. Hold the inhaler upright with the mouthpiece at the bottom and place the mouthpiece between your teeth without biting it. Then place your lips around the mouthpiece, with the tongue flat under it.
4. Breathe in slowly and deeply through your mouth to fill your lungs with air (this should take about 4–5 seconds). Just after starting to breathe in, press down firmly on the top of the pressurised container to release one puff.
5. Hold your breath for as long as possible and, finally, remove the inhaler from your mouth and breathe out slowly. Do not breathe out into the inhaler.
6. Check that the dose counter (60/120 puffs) has moved down by one or that the dose indicator (180 puffs) has rotated by a small amount.

For the second puff, keep the inhaler in the upright position for about half a minute, then repeat steps 2 to 5.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that Trimbow will not be getting into your lungs as it should. Take another puff, following the instructions starting again from step 2.

After use, replace the protective cap.

To prevent a fungal infection in the mouth and throat, rinse your mouth or gargle with water without swallowing it or brush your teeth after each use of your inhaler.

When to get a new inhaler
You should get a replacement when the counter or indicator shows the number 20. Stop using the inhaler when the counter or indicator shows 0, as any medicine left in the inhaler may not be enough to give you a full puff.

If you have a weak grip, it may be easier to hold the inhaler

with both hands: hold the upper part of the inhaler with both index fingers and its lower part with both thumbs.

If you find it difficult to use the inhaler while starting to breathe in, you may use the AeroChamber Plus spacer device. Ask your doctor or pharmacist about this device. It is important that you read the package leaflet which is supplied with your AeroChamber Plus spacer device and that you carefully follow the instructions on how to use the AeroChamber Plus spacer device and how to clean it.

Cleaning of the Trimbow inhaler

You should clean your inhaler once a week.

1. Do not remove the pressurised container from the inhaler and do not use water or other liquids to clean your inhaler.
2. Remove the protective cap from the mouthpiece by pulling it away from your inhaler.
3. Wipe inside and outside of the mouthpiece and the inhaler with a clean, dry cloth or tissue.
4. Replace the mouthpiece cap.

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
- pain in the back of the mouth and throat
- weakness
- 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 freeze.
Do not expose to temperatures higher than 50°C.
Do not pierce the pressurised container.

Prior to dispensing:
Store in a refrigerator (2°C-8°C).

After dispensing (receiving this medicine from your pharmacist):
60 actuation pressurised container: Store the inhaler below 25°C for a maximum of 2 months.
120 (from a single or multipack) and
180 actuation pressurised container: Store the inhaler below 25°C for a maximum of 4 months.

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 87 micrograms of beclometasone dipropionate, 5 micrograms of formoterol fumarate dihydrate and 9 micrograms of glycopyrronium (as 11 micrograms glycopyrronium bromide).

Each metered dose (the dose leaving the valve) 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: ethanol anhydrous (see section 2), hydrochloric acid, propellant: norflurane.

What Trimbow looks like and contents of the pack

Trimbow is a pressurised inhalation, solution.
Trimbow comes in a pressurised container (coated

aluminium), with a metering valve. The pressurised container is inserted in a plastic inhaler. This incorporates a mouthpiece provided with a plastic protective cap, and either a dose counter (containers with 60 and 120 puffs) or a dose indicator (containers with 180 puffs).

Each pack contains one pressurised container either providing 60 puffs, 120 puffs or 180 puffs. Additionally there are multipacks containing either 240 puffs (2 pressurised containers with 120 puffs, each) or 360 puffs (3 pressurised containers with 120 puffs, each).

Not all pack sizes may be marketed.

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