PACKAGE LEAFLET: INFORMATION FOR THE USER

Proxor 200/6 micrograms per actuation pressurised inhalation, solution

beclometasone dipropionate/ formoterol fumarate dihydrate

For use in adults

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Proxor is and what it is used for

Proxor is a pressurised inhalation solution containing two active substances which are inhaled through your mouth and delivered directly into your lungs.

The two active substances are beclometasone dipropionate and formoterol fumarate dihydrate.

Beclometasone dipropionate belongs to a group of medicines called corticosteroids which have an anti-inflammatory action reducing the swelling and irritation in your lungs.

Formoterol fumarate dihydrate belongs to a group of medicines called long-acting bronchodilators which relax the muscles in your airways and helps you to breathe more easily.

Together these two active substances make breathing easier, by providing relief from symptoms such as shortness of breath, wheezing and cough in patients with asthma or COPD and also help to prevent the symptoms of asthma.

Proxor is used to treat asthma in adults.

If you are prescribed Proxor it is likely that either:
- your asthma is not adequately controlled by using inhaled corticosteroids and “as needed” short-acting bronchodilators or
- your asthma responds well to both corticosteroids and long-acting bronchodilators

2. What you need to know before you use Proxor

Do not use Proxor:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Proxor:
- If you have any heart problems, such as angina (heart pain, pain in the chest), heart failure, narrowing of the arteries, valvular heart disease or any other known abnormalities of your heart
- If you have high blood pressure or if you know that you have an aneurysm (an abnormal bulging of the blood vessel wall).
- If you have disorders of your heart rhythm such as increased or irregular heart rate, a fast pulse rate or palpitations or if you have been told that your heart trace is abnormal.
- If you have an overactive thyroid gland.
- If you have low blood levels of potassium.
- If you have any disease of your liver or kidneys.
- If you have diabetes (if you inhale high doses of formoterol your blood glucose may increase and therefore you may need to have some additional blood tests to check your blood sugar when you start using this inhaler 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 taking Proxor at least 12 hours before the anaesthesia.
- If you are being, or have ever been, treated for tuberculosis (TB) or if you have a known viral or fungal infection of your chest.
- If you must avoid alcohol **for any reason.**

If any of the above applies to you, always inform your doctor before you use Proxor.

If you have or had any medical problems or allergies or if you are not sure whether you can use Proxor talk to your doctor, asthma nurse or pharmacist before using this medicine.

Your doctor may wish to measure the potassium levels in your blood from time to time especially if your asthma is severe.

Like many bronchodilators Proxor can cause a sharp fall in your serum potassium level (hypokalaemia). This is because a lack of oxygen in the blood combined with some other treatments you may be taking together with Proxor can make the fall in potassium level worse.

If you take higher doses of inhaled corticosteroids over long periods, you may have more of a need for corticosteroids in situations of stress. Stressful situations might include being taken to hospital after an accident, having a serious injury or before an operation. In this case, the doctor treating you will decide whether you may need to increase your dose of corticosteroids and may prescribe some steroid tablets or a steroid injection.

Should you need to go to the hospital, remember to take all of your medicines and inhalers with you, including Proxor and any medicines or tablets bought without a prescription, in their original packaging, if possible.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

Proxor should not be used in children and adolescent less than 18 years old, until further data become available.

Other medicines and Proxor:

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. This is because Proxor may affect the way some other medicines work. Also, some medicines may affect the way Proxor works.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:
- Some medicines may increase the effects of Proxor and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).
- Beta-blocker medicines. Beta blockers are medicines used to treat many conditions including heart problems, high blood pressure and glaucoma (increased pressure in the eyes). If you need to use beta blockers including eye drops, the effect of formoterol may be reduced or formoterol may not work at all.
- Beta adrenergic drugs (drugs which work in the same way as formoterol) may increase the effects of formoterol.
- Medicines for treating abnormal heart rhythms (quinidine, disopyramide, procainamide).
- Medicines used to treat allergic reactions (antihistamines).
- Medicines to treat symptoms of depression or mental disorders such as monoaminoxidase inhibitors (for example phenelzine and isocarboxazid), tricyclic antidepressants (for example amitryptiline and imipramine), phenothiazines.
- Medicines to treat Parkinson’s Disease (L-dopa).
- Medicines to treat an underactive thyroid gland (L-thyroxine).
- Medicines containing oxytocin (which causes uterine contraction).
- Medicines to treat mental disorders such as monoaminoxidase inhibitors (MAOIs), including drugs with similar properties like furazolidone and procarbazine.
- Medicines to treat heart disease (digoxin).
- Other medicines used to treat asthma (theophylline, aminophylline or steroids).
- Diuretics (water tablets).

Also tell your doctor if you are going to have a general anaesthetic for an operation or for dental work.

Pregnancy, breast- feeding and fertility

There are no clinical data on the use of Proxor during pregnancy.

Proxor should not be used if you are pregnant, think that you might be pregnant or are planning to become pregnant, or if you are breast-feeding, unless you are advised to do so by your doctor.

Driving and using machines

Proxor is unlikely to affect your ability to drive and use machines. However, if you experience side effects such as dizziness and/or trembling, your ability to drive or operate machinery may be affected.

Proxor contains alcohol

Proxor contains 9 mg of alcohol (ethanol) in each actuation which is equivalent to 0.25 mg/kg 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 Proxor

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

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of Proxor. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms.

Dosage:

Adults and the elderly:

The recommended dose of this medicine is one or two puffs twice daily. The maximum daily dose is 4 actuations.

Remember: You should always have your quick-acting “reliever” inhaler with you at all times to treat worsening symptoms of asthma or a sudden asthma attack.

At-risk patients:

Older people do not need to have their dose adjusted. No information is available regarding the use of Proxor in people with liver or kidney problems.

Use in children and adolescents less than 18 years of age:

Children and adolescents aged less than 18 years must **NOT** take this medicine.

Proxor is effective for the treatment of asthma in a dose of beclometasone dipropionate which may be lower than that of some other inhalers containing beclometasone dipropionate. If you have been using a different inhaler containing beclometasone dipropionate previously, your doctor will advise you on the exact dose of Proxor you should take for your asthma.

Do not increase the dose

If you feel that the medicine is not very effective, always talk to your doctor before increasing the dose.

If your asthma gets worse:

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

Method of administration:

Proxor is for inhalation use

This medicine is contained in a pressurised canister in a plastic casing with a mouthpiece. There is a counter on the back of the inhaler for the 120 doses actuations and a dose indicator for the 180 actuations, which tells you how many doses are left.

For the pack size containing 120 actuations, each time you press the canister, 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.

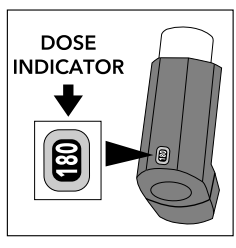
For the pack size containing 180 actuations, the dose indicator will show the approximate number of actuations (sprays) remaining in the canister. The dose-indicator window displays the number of sprays left in the inhaler in units of twenty (e.g., 180, 120, 100, 80, etc). When 20 actuations remain, so that the display shows the number 20 it indicats that the canister is closer to its end of life.

When 180 actuations have been discharged, the display shows the number 0.

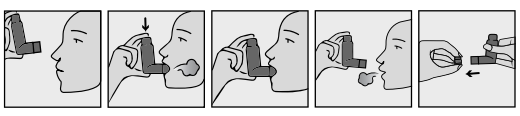
The indicator will stop moving at “0”.

Testing your inhaler

Before using the inhaler for the first time or if you have not used the inhaler for 14 days or more, you should test your inhaler to make sure that it is working properly.
- Remove the protective cap from the mouthpiece
- Hold your inhaler upright with the mouthpiece at the bottom
- Direct the mouthpiece away from yourself
- If you are using the inhaler for the first time firmly depress the canister 1 time to release a puff to depress the canister.
- If you have not used the inhaler for 14 days or more firmly depress the canister once to release one puff.
- For the pack size containing 120 actuation check the dose counter. If you are testing your inhaler for the first time, the counter should read 120.
- For the pack size containing 180 actuation check the dose indicator. If you are testing your inhaler for the first time, the counter should read 180.



How to use your inhaler
Whenever possible, stand or sit in an upright position when inhaling.
Before you start inhaling, check the dose counter or dose indicator that shows how many doses are left. If the dose counter or dose indicator shows "0" there are no doses left – dispose of your inhaler and get a new one.



1. Remove the protective cap from the mouthpiece and check that the mouthpiece is clean and free from dust and dirt or any other foreign objects.
2. Breathe out as slowly and deeply as possible.
3. Hold the canister vertically with its body upwards and put your lips around the mouthpiece. Do not bite on the mouthpiece.
4. Breathe in slowly and deeply through your mouth and, just after starting to breathe in press down firmly on the top of the inhaler to release one puff. If you have weak hands, 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.
5. Hold your breath for as long as possible and, finally, remove the inhaler from your mouth and breathe out slowly. Do not breathe into the inhaler.

If you need to take another puff, keep the inhaler in the vertical position for about half a minute, then repeat steps 2 to 5.

Important: Do not perform steps 2 to 5 too quickly.

After use, close with the protective cap and check the dose counter for the pack size containing 120 doses and the dose indicator for the pack size containing 180 actuations.

To lower the risk of a fungal infection in the mouth and throat, rinse your mouth, gargle with water or brush your teeth each time you use your inhaler.

When to replace your inhaler

You should get a replacement when the counter or the dose indicator shows the number 20. Stop using the inhaler when the counter shows 0 as any puffs left in the device may not be enough to give you a full dose.

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

If you think the effect of Proxor is too much or not enough, tell your doctor or pharmacist.

If you find it difficult to operate the inhaler while starting to breathe in you may use the AeroChamber Plus spacer device. Ask your doctor, pharmacist or a nurse about this device.

It is important that you read the package leaflet which is supplied with your AeroChamber Plus spacer device and that you follow the instructions on how to use and how to clean it, carefully.

Cleaning
You should clean your inhaler once a week.

When cleaning, do not remove the canister from the actuator and do not use water or other liquids to clean your inhaler.

To clean your inhaler:
1. Remove the protective cap from the mouthpiece by pulling it away from your inhaler.
2. Wipe inside and outside of the mouthpiece and the actuator with a clean, dry cloth or tissue.
3. Replace the mouthpiece cover

If you use more Proxor than you should:
- Taking more formoterol than you should can have the following effects: feeling sick, being sick, heart racing, palpitations, disturbances of heart rhythm, certain changes in the electrocardiogram (heart trace), headache, trembling, feeling sleepy, too much acid in the blood, low blood potassium levels, high levels of glucose in the blood. Your doctor may wish to carry out some blood tests to check your blood potassium and blood glucose levels.
- Taking too much beclometasone dipropionate can lead to short-term problems with your adrenal glands. This will get better within a few days however your doctor may need to carry out some blood tests to check your serum cortisol levels.

Tell your doctor if you have any of these symptoms.

If you forget to use Proxor:
Take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the correct time. **Do not double the dose.**

If you stop using Proxor:
Do not lower the dose or stop using the medication.
Even if you are feeling better, do not stop taking Proxor or lower the dose. If you want to do this, talk to your doctor. It is very important for you to use Proxor regularly even though you may have no symptoms.

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

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

As with other inhaler treatments there is a risk of worsening shortness of breath and wheezing immediately after using Proxor and this is known as **paradoxical bronchospasm.** If this occurs, you should **STOP using Proxor immediately** and use your quick-acting "reliever" inhaler straightaway to treat the symptoms of shortness of breath and wheezing. You should contact your doctor straightaway.

Tell your doctor immediately if you experience any **hypersensitivity reactions** like skin allergies, skin itching, skin rash, reddening of the skin, swelling of the skin or mucous membranes especially of the eyes, face, lips and throat.

Other possible side effects are listed below according to their frequency.

Common (may affect up to 1 in 10 people):
- fungal infections (of the mouth and throat)
- headache
- hoarseness
- sore throat

Uncommon (may affect up to 1 in 100 people):
- palpitations, unusually fast heart beat and heart rhythm disorders
- some changes in the electrocardiogram (ECG)
- increase in blood pressure
- flu like symptoms
- sinus inflammation
- rhinitis
- inflammation of the ear
- throat irritation
- cough and productive cough
- asthma attack
- fungal infections of the vagina
- nausea
- abnormal or impaired sense of taste
- burning of the lips
- dry mouth
- swallowing difficulties
- indigestion
- upset stomach
- diarrhoea
- pain in muscle and muscle cramps
- reddening of the face and throat
- increased blood flow to some tissues in the body
- excessive sweating
- trembling
- restlessness
- dizziness
- nettle rash or hives
- alterations of some constituents of the blood:
  - fall in the number of white blood cells
  - increase in the number of blood platelets
  - fall in the level of potassium in the blood
  - increase in blood sugar level
  - increase in the blood level of insulin, free fatty acid and ketones

The following side effects have also been reported as "uncommon" in patients with chronic obstructive pulmonary disease:
- pneumonia; tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum colour, fever, increasing cough, increased breathing problems
- reduction of the amount of cortisol in the blood; this is caused by the effect of corticosteroids on your adrenal gland
- irregular heart beat

Rare (may affect up to 1 in 1,000 people):
- chest tightness
- missed heartbeat (caused by premature contraction of the heart's ventricles)
- decrease in blood pressure
- kidney inflammation
- swelling of skin and mucous membrane persisting for several days

Very rare (may affect up to 1 in 10,000 people):
- shortness of breath
- worsening of asthma
- a fall in the number of blood platelets
- swelling of the hands and feet

Using high-dose inhaled corticosteroids over a long time can cause in very rare cases systemic effects. These include:
- problems with how your adrenal glands work (adreno-suppression)
- decrease in bone mineral density (thinning of the bones)
- growth retardation in children and adolescents
- increased pressure in your eyes (glaucoma)
- cataracts

Unknown (frequency cannot be estimated from the available data):
- sleeping problems
- depression or anxiety
- nervousness
- feeling over-excited or irritable.

These events are more likely to occur in children
- Blurred vision

Reporting of side effects
If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 Proxor
Keep this medicine out of the sight and reach of children.

Before use: store the inhaler in a refrigerator (at 2-8°C) for a maximum of 18 months.

After first use: Use the inhaler for a maximum of three months and do not store above 25 °C. Do not use the inhaler after this period and never use it after the expiry date which is stated on the carton and label after "EXP". Expiry date refers to the last day of that month. Do not freeze.

If the inhaler has been exposed to severe cold, warm it with your hands for a few minutes before using. Never warm it by artificial means.

Warning: The canister contains a pressurised liquid. Do not expose the canister to temperatures higher than 50 °C. Do not pierce the canister.

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 to protect the environment.

6. Contents of the pack and other information

What Proxor contains:
The active substances are: beclometasone dipropionate, formoterol fumarate dihydrate.

Each actuation/metered dose from the inhaler contains 200 micrograms of beclometasone dipropionate and 6 micrograms of formoterol fumarate dihydrate. This corresponds to a delivered dose from the mouthpiece of 177.7 micrograms of beclometasone dipropionate and 5.1 micrograms of formoterol fumarate dihydrate.

The other ingredients are: norflurane (HFA 134-a), ethanol anhydrous, hydrochloric acid.

This medicine contains fluorinated greenhouse gases.

Each inhaler of 120 actuation contains 10.35 g of HFC-134a corresponding to 0.015 tonne CO2 equivalent (global warming potential GWP = 1,430).

Each inhaler of 180 actuation contains 14.24 g of HFC-134a corresponding to 0.020 tonne CO2 equivalent (global warming potential GWP = 1,430).

What Proxor looks like and contents of the pack:
Proxor is a pressurised inhalation solution contained in an aluminium canister with a metering valve, fitted in a plastic actuator which incorporates a dose counter (120 actuations pack) or a dose indicator (180 actuations pack), with a green plastic protective cap.

Each pack contains:
1 pressurised container which provides 120 actuations (puffs) or
2 pressurised containers which provide 120 actuations each or
3 pressurised containers which provide 120 actuations each or
1 pressurised container which provides 180 actuations

Not all pack sizes may be marketed.

Marketing authorisation holder:
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer responsible for batch release:
Genetic S.p.A., Contrada Canfora, 84084 Fisciano (SA), Italy.

This leaflet was last revised in October 2024.