PACKAGE LEAFLET: INFORMATION FOR USER

PREVENTER

Soprobec 50 micrograms per actuation pressurised inhalation solution
Soprobec 100 micrograms per actuation pressurised inhalation solution
Soprobec 200 micrograms per actuation pressurised inhalation solution
Soprobec 250 micrograms per actuation pressurised inhalation solution
beclometasone dipropionate

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

1. What Soprobec is and what it is used for

Soprobec pressurised inhalation solution is used to help **prevent** the symptoms of asthma**.** The active ingredient, beclometasone dipropionate, is one of a group of medicines called corticosteroids which are often referred to simply as steroids. Steroids have an anti-inflammatory action reducing the swelling and irritation in the walls of the small air passages in the lungs, and so ease breathing problems.

2. What you need to know before you use Soprobec

Do not use Soprobec:
- if you are allergic to any of the ingredients of this medicine or to any other medicines used to treat asthma.
- **to treat a sudden attack of breathlessness**. It will not help. Use a quick-acting 'reliever' inhaler for this purpose and carry it with you at all times.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Soprobec if any of the following applies to you:
- you are being, or have ever been, treated for tuberculosis (TB).
- you had thrush in your mouth.
- you must avoid alcohol for any reason.

Also, talk to your doctor, pharmacist or nurse if any of the following applies to you:

- your asthma seems to be getting worse. Perhaps you are more wheezy and short of breath than usual, your 'reliever' inhaler seems to be less effective, you require more puffs from your 'reliever' inhaler than usual, or you do not seem to be getting better.
- when transferring from steroid tablets to an inhaler you find that, even if your chest is getting better, you feel generally unwell, you develop a rash, eczema or a runny nose and sneezing (rhinitis). **Do not stop** treatment with your inhaler unless your doctor tells you to.

If you have been treated for a long time with high doses of inhaled steroid, you may require a course of steroid tablets or possibly a steroid injection in times of stress. For example, during admission to hospital after a serious accident, before an operation, during an acute attack of asthma or if you have a chest infection or other serious illness. Your doctor will decide if you need any extra steroid treatment and will also advise you as to how long you need to take the course of steroid tablets and how you should reduce these as you get better.

If you are using Soprobec instead of, or as well as taking steroid tablets, or if your doctor is trying to reduce the dose of your steroid tablets, you should carry a steroid warning card until your doctor tells you that you don't need to.

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

Other medicines and Soprobec:
Before starting treatment, please tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking disulfiram or metronidazole, as there is a potential risk of interaction in particularly sensitive people.

Remember to take these medicines and your inhalers with you if you have to go into hospital.

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

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 taking this medicine.

Driving and using machines:
Soprobec is not likely to affect the ability to drive or use machines.

Soprobec contains alcohol:
Soprobec 50 and 100 micrograms:
This medicine contains 7.47 mg of alcohol (ethanol) in each actuation which is equivalent to 13% w/w.
Soprobec 200 micrograms:
This medicine contains 8.05 mg of alcohol (ethanol) in each actuation which is equivalent to 14% w/w.
Soprobec 250 micrograms:
This medicine contains 8.62 mg of alcohol (ethanol) in each actuation which is equivalent to 15% w/w.
The amount of alcohol in each actuation is equivalent to less than 4 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Soprobec
Soprobec is available in 4 different strengths. Your doctor will have decided which strength you need. Soprobec 200 and Soprobec 250 are not suitable for children.

Always use your inhaler exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Instructions for using your inhaler are given after the dosage section. It takes a few days for your inhaler to work. It is very important that you use it regularly.

Do not stop treatment even if you feel better unless told to do so by your doctor. **Do not stop** using

your inhaler abruptly.

While you are using Soprobec your doctor will want to check your asthma regularly by carrying out simple breathing tests and may need to carry out blood tests from time to time.

Dosage:
The starting dose will depend on how severe your asthma is and will be decided by your doctor. It may be higher than the doses given below. Your doctor will prescribe the lowest dose of Soprobec that will control your symptoms.

A device called a Volumatic spacer should always be used when:

- adults, the elderly and adolescents 16 years of age and older are taking total daily doses of Soprobec of 1,000 micrograms or more,
- when Soprobec is used in children and adolescents 15 years of age and under whatever dose has been prescribed.

Soprobec 50 micrograms
The common starting dose is:
Adults and the elderly: 200 micrograms (4 puffs) twice a day
Children: 100 micrograms (2 puffs) twice a day

Usually the most you would take in a day is:
Adults and the elderly: 800 micrograms (16 puffs)
Children: 400 micrograms (8 puffs)

The total daily dose may be divided into 2, 3 or 4 doses per day.

Soprobec 100 micrograms
The common starting dose is:
Adults and the elderly: 200 micrograms (2 puffs) twice a day
Children: 100 micrograms (one puff) twice a day

Usually the most you would take in a day is:
Adults and the elderly: 800 micrograms (8 puffs)
Children: 400 micrograms (4 puffs)

The total daily dose may be divided into 2, 3 or 4 doses per day.

Soprobec 200 micrograms
The common starting dose is:
Adults and the elderly only: 200 micrograms (1 puff) twice a day
Usually the most you would take in a day is: 800 micrograms (4 puffs)

The total daily dose may be divided into 2, 3 or 4 doses per day.

This product strength is not suitable for children

Soprobec 250 micrograms
The common starting dose is:
Adults and the elderly only: 500 micrograms (2 puffs) twice a day
Usually the most you would take in a day is: 2,000 micrograms (8 puffs)

The total daily dose may be divided into 2, 3 or 4 doses per day.

This product strength is not suitable for children

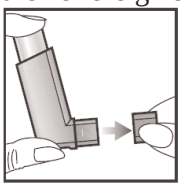
If you use more Soprobec than you should:
Tell your doctor as soon as possible. Your doctor may want to check the cortisol levels in your blood and therefore, may need to take a blood sample (cortisol is a steroid hormone which occurs naturally in the body).
It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you forget to use Soprobec:
Do not take a double dose to make up for a forgotten dose. Take the next dose when it is due. Do not take more puffs than you were told to take.

Method of Administration
Soprobec is for inhalation use.

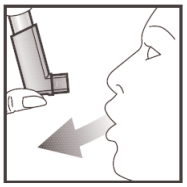
Instructions for use:
It is important that you know how to use your inhaler properly. Your doctor, nurse or pharmacist will show you how to use your inhaler correctly and will check regularly that you are using your inhaler correctly. You must follow their instructions carefully, so that you know **how, when** and **how many** puffs to inhale and how often you must use your inhaler. The instructions should be on the pharmacist's label and are given in this leaflet. If you are not sure what to do or have problems inhaling then ask your doctor, nurse or pharmacist for advice.

1. To remove the mouthpiece cover, hold between the thumb and forefinger, squeeze gently and pull apart as shown. Check inside and outside to make sure that the mouthpiece is clean, and that there are no foreign objects.

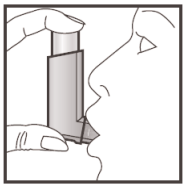


Testing Your Inhaler: If the inhaler is new or if it has not been used for three days or more, one puff should be released into the air to make sure that it works.

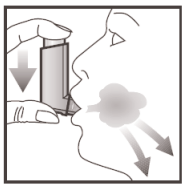
2. Hold the inhaler upright as shown, with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable.



3. Place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.

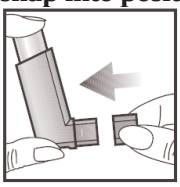


4. Just after starting to breathe in through your mouth press down on the top of the inhaler to release a puff while still breathing in steadily and deeply



5. Hold your breath; take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds or as long as is comfortable. Breathe out slowly.
6. If you are to take another puff, keep the inhaler upright and wait about half a minute before repeating steps 2 to 5.

7. After use always replace the mouthpiece cover to keep out dust and fluff. **Replace firmly and snap into position.**



Important: Do not rush steps 2, 3, 4 and 5.

It is important that you start to breathe in as slowly as possible just before operating the inhaler. Practice in front of a mirror for the first few times.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, beclometasone will not get into your lungs as it should. Take another puff, carefully following the instructions from Step 2 onwards.

People with weak hands or children may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece.

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

However, the Volumatic spacer device must always be used if**:**
- You are an adult, elderly or an adolescent 16 years of age and older and are taking total daily doses of Soprobec of 1,000 micrograms or more,
- Soprobec is used in children and adolescents 15 years of age and younger, whatever dose has been prescribed.

Young children may find it difficult to use the inhaler properly and will require help. Using the inhaler with the Volumatic spacer device with a face mask may help in children under 5 years. **Tell your doctor, nurse or pharmacist if you have any difficulties.**

Cleaning:
It is important to clean your inhaler at least once a week, to stop it blocking up.
- Pull the metal canister out of the plastic case of the inhaler and remove the mouthpiece cover.
- Rinse the plastic case and the mouthpiece cover in warm water**.** If you use a mild liquid detergent, rinse carefully with clean water before drying. Do not put the metal canister into water.
- Leave to dry thoroughly in a warm place. Avoid excessive heat.

- Replace the canister and mouthpiece cover.

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

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

Stop using Soprobec and contact your doctor immediately if:
- **you get allergic reactions including skin rashes, hives, itching or redness, or swelling of the face, eyes, lips and throat.**
- **you notice an immediate increase in wheezing, shortness of breath and cough straight after using your inhaler, stop** using Soprobec and use a quick-acting 'reliever' inhaler immediately. Contact your doctor straightaway. Your doctor will review your asthma and may change your treatment and may prescribe a different inhaler to treat your asthma.

The following side effects have been reported. **Tell your doctor as soon as possible** if you suffer from any of these side effects but **do not stop treatment** unless told to do so. Your doctor will try to prevent these effects by prescribing Soprobec in the lowest dose possible to control your asthma.

Very common (may affect more than 1 in 10 people)
- Candidiasis in the mouth and / or throat (thrush). This is more likely if the daily dose taken is greater than 400 micrograms. Thrush can be treated with anti-fungal medicines whilst you continue to use Soprobec. Brushing your teeth, or thoroughly rinsing your mouth with water immediately after each dose may help prevent thrush.

Common (may affect up to 1 in 10 people)
- Hoarse voice or a sore throat or tongue**.** Using a Volumatic spacer device or rinsing your mouth with water immediately after using your inhaler may help prevent this.

Uncommon (may affect up to 1 in 100 people)
- Rash, hives, pruritus and / or erythema.

Very rare (may affect up to 1 in 10,000 people)
- Allergies, which manifest with swelling of the eyelids, face, lips and / or throat (angioedema).
- Respiratory disturbances such as dyspnea (feeling of shortness of breath or difficulty breathing) and / or bronchospasm (narrowing of the walls of the bronchi with decreased air intake).
- Anaphylactic or anaphylactoid reactions (severe allergic reactions that can make breathing difficult or alter your level of consciousness).
- Children and adolescents may grow more slowly and may need to have their height checked regularly by their doctor. This occurs particularly after treatment with Soprobec at high doses over a long period of time.
- Rounded face (full moon) (Cushing's syndrome).
- A decrease in bone mineral density (thinning and weakening of the bones).
- Eye problems which include the formation of cataracts and glaucoma (increased pressure in the eye).
- Paradoxical bronchospasm.

Frequency not known:
- **Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to appear in children.**
- **Blurry vision**
- **Headache,**

- **Nausea**

· If you **become unwell** or develop symptoms such as **loss of appetite**, abdominal pain, weight loss, tiredness, nausea (feeling sick), vomiting (being sick), feeling faint, sweating and possible convulsions (fits), you should consult your doctor. This is particularly important if you have been exposed to stress such as surgery, infection, an acute attack of asthma, or other serious illness.
Your doctor may carry out blood test from time to time to monitor the levels of steroids in your body.

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 at 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 Soprobec
· **Keep this medicine out of the sight and reach of children.**
· Do not use Soprobec after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.
· Do not freeze.
· Store in the original package in order to protect from the light.

· If the inhaler gets very cold, take the metal canister out of the plastic case and warm it **in your hands** for a few minutes before use. **Neve**r use anything else to warm it up.
· 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.

Warning: The canister contains a pressurised liquid. Keep away from heat and direct sunlight, do not expose to high temperatures (above 50°C) and do not puncture or burn (incinerate), even when empty.

6. Contents of the pack and other information
What Soprobec contains
The active substance of your inhaler is beclometasone dipropionate. Each puff contains 50, 100, 200 or 250 micrograms of beclometasone dipropionate.
The other ingredients are glycerol, ethanol and the CFC-free propellant norflurane (HFC-134a).

This medicine contains fluorinated greenhouse gases.
50mcg:
Each inhaler contains 11.808 g of HFC-134a corresponding to 0.017 tonne CO_2 equivalent (global warming potential = 1430)
100 mcg:
Each inhaler contains 11.796 g of HFC-134a corresponding to 0.017 tonne CO_2 equivalent (global warming potential = 1430)
200 mcg:
Each inhaler contains 11.634 g of HFC-134a corresponding to 0.017 tonne CO_2 equivalent (global warming potential = 1430)
250 mcg:
Each inhaler contains 11.484 g of HFC-134a corresponding to 0.016 tonne CO_2 equivalent (global warming potential = 1430)

To help protect the environment, the inhaler contains the CFC-free propellant HFC-134a, which replaces completely the chlorofluorocarbon (CFC) propellants and appears to have a less damaging effect on the ozone layer. The only differences you might notice from your previous CFC-containing inhaler are the taste and the feel of the spray in your mouth.

What Soprobec looks like and content of the pack
50mcg:
Soprobec is a pressurised inhalation solution contained in an aluminium can with cream coloured plastic actuator and dark brown colour protective cap. Each pack contains either a single inhaler, or two inhalers. Each canister contains 200 puffs.
100mcg:
Soprobec is a pressurised inhalation solution contained in an aluminium can with grey coloured plastic actuator and light pink colour protective cap. Each pack contains either a single inhaler, or two inhalers. Each canister contains 200 puffs.
200mcg:
Soprobec is a pressurised inhalation solution contained in an aluminium can with pink coloured plastic actuator and red colour protective cap. Each pack contains either a single inhaler, or two inhalers. Each canister contains 200 puffs.
250mcg:
Soprobec is a pressurised inhalation solution contained in an aluminium can with light maroon coloured plastic actuator and grey colour protective cap. Each pack contains either a single inhaler, or two inhalers. Each canister contains 200 puffs.

Not all pack sizes may be marketed.

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The leaflet was last revised in August 2026.

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