

BECEZE CFC FREE PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BECEZE 50 CFC FREE pressurised inhaler, solution
BECEZE 100 CFC FREE pressurised inhaler, solution
BECEZE 250 CFC FREE pressurised inhaler, solution
Beklometasondipropionate

Read all of this leaflet carefully before you start using BECEZE CFC FREE:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BECEZE CFC FREE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What BECEZE CFC FREE is and what it is used for
 2. What you need to know before you use BECEZE CFC FREE
 3. How to use BECEZE CFC FREE
 4. Possible side effects
 5. How to store BECEZE CFC FREE
 6. Contents of the pack and other information
- BECEZE CFC FREE contains beklometasondipropionate, which is one of a group of medicines called corticosteroids and 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.**
- BECEZE CFC FREE is used for the management of patients with bronchial asthma, including patients whose asthmatic condition is expected to require long-term steroid maintenance therapy and patients whose asthma is incompletely controlled by bronchodilator therapy alone or in combination with sodium cromoglicate.**
- BECEZE CFC FREE is effective in managing asthma in children, without suppressing growth, which is normally associated with systemic steroids.**

2. What you need to know before you use BECEZE CFC FREE

- Do not use BECEZE CFC FREE:**
- If you are hypersensitive (allergic) to beklometasondipropionate or any of the other ingredients of BECEZE CFC FREE (listed in section 6).
 - If you are pregnant.
 - If you have severe worsening of asthma that does not respond to standard treatment.
 - BECEZE CFC FREE should be used with caution in patients with tuberculosis (TB) or those with a history of tuberculosis.

Warnings and precautions:

BECEZE CFC FREE is a preventative asthma medicine and should not be used for the treatment of an acute asthma attack; you should always have your relief medication nearby.

You must use your BECEZE CFC FREE inhaler regularly and as per your doctor's instructions, even if you don't experience any asthma symptoms.

A therapeutic effect is only achieved after a few days of use; you should thus not stop your treatment early if you don't feel immediate relief.

Your doctor should examine you regularly if you have severe asthma, including lung-function testing, as you may have a higher risk for a severe attack, which can be fatal.

You should seek medical attention if your therapy becomes less effective, or if you require more inhalations of BECEZE CFC FREE as this may indicate deterioration of asthma control. Your doctor will assess you and increase your anti-inflammatory medication if needed.

If you experience severe worsening of your asthma, your doctor may increase your dosage of BECEZE CFC FREE, give you a systemic steroid, and prescribe an appropriate antibiotic if you have an infection, together with medicine that relaxes the muscles in your airways.

When transferring from steroid tablets to BECEZE CFC FREE, you may find that, even if your chest is better, you feel generally unwell. You may develop a runny nose or a sore throat and sneezing (rhinitis). Do not stop treatment with your BECEZE CFC FREE unless your doctor tells you to.

Prolonged and excessive use of BECEZE CFC FREE may lead to systemic corticosteroid effects. These effects include: adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma and less frequently, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (especially in children).

It is recommended that the height of children on prolonged treatment with BECEZE CFC FREE be monitored regularly. If the child's growth is slowed, asthma therapy should be reviewed with the aim of reducing the dose of BECEZE CFC FREE, to the lowest dose at which asthma control is maintained. The child should be referred to a paediatric respiratory specialist.

Your doctor will give you additional asthma medicines in appropriate cases of stress or before elective surgery.

Your doctor may lower the dosage of your other asthma medication when introducing BECEZE CFC FREE, the transfer between medication will be done slowly, and if you are in a reasonably stable condition.

Your doctor will monitor any related infections, and treat it appropriately.

Thrush infection may occur in the mouth and throat of some patients, depending on the dose of BECEZE CFC FREE. If you suffered a previous thrush infection, you are more likely to develop this complication. You may find it helpful to rinse your mouth with water after using your inhaler. Your doctor will treat your oral thrush with a topical antifungal therapy, while you continue to use BECEZE CFC FREE.

If you develop a throat irritation or hoarseness, you may find it helpful to rinse your mouth and throat with water after each dose of BECEZE CFC FREE to remove residual medication.

If you experience an immediate increase in wheezing, shortness of breath and coughing after using BECEZE CFC FREE, you should immediately use a fast-acting bronchodilator inhaler to treat it, and notify your doctor, who will assess you and introduce another asthma therapy.

If you experience blurred vision or any other changes in your vision, please speak to your doctor (see section 4).

Children and adolescents:
If your child is receiving prolonged treatment with BECEZE CFC FREE, your doctor should regularly monitor their height to evaluate if growth impairment occurs.

Other medicines and BECEZE CFC FREE:
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

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

BECEZE CFC FREE contains ethanol. Tell your doctor or healthcare provider if you are using medicine where you should avoid the use of alcohol. These medicines contain disulfiram (a medicine used to treat alcoholism) and metronidazole (an antibiotic and antiprotozoal medicine).

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using BECEZE CFC FREE.

You should not use BECEZE CFC FREE if you are pregnant or breastfeeding.

Driving and using machines:
You should use caution when driving a car or operating machinery until you are reasonably certain that your ability to perform such activities is not affected by BECEZE CFC FREE.

BECEZE CFC FREE contains ethanol:
BECEZE CFC FREE contains approximately 2 mg alcohol (ethanol) per inhalation (puff). The small amount of ethanol in BECEZE CFC FREE will not have any noticeable effects. Also see section "Other medicines and BECEZE CFC FREE".

3. How to use BECEZE CFC FREE
Do not share medicines prescribed for you with any other person.
Always use BECEZE CFC FREE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

BECEZE CFC FREE is for oral inhalation use only.
The usual dosage is:
Children: 50 to 100 µg, inhaled 2, 3 or 4 times daily according to your child's age and response.
Alternatively, 100 µg or 200 µg can be inhaled twice a day.

Adults: 200 µg twice daily, up to a maximum of 1 mg (1 000 µg daily) in 2, 3 or 4 divided doses, according to your response.

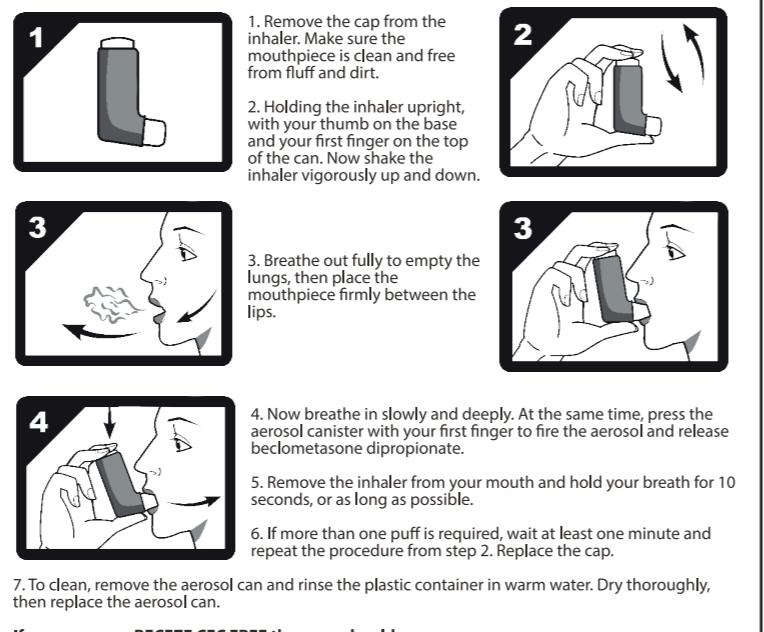
Do not exceed the recommended dose.

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

Your doctor will tell you how long your treatment will last. BECEZE CFC FREE treatment should not be stopped suddenly. Your doctor will adjust your dosage to the lowest dose at which effective control of asthma is maintained. If you have the impression that the effect of BECEZE CFC FREE is too strong or too weak, tell your doctor or pharmacist.

HOW TO USE YOUR INHALER:

It is essential that the beklometasondipropionate inhaler is fired at the same time as you breathe in. If you have not used an inhaler before, it may be useful to practice steps 3 and 4 of the diagram without actually triggering the inhaler, so that breathing in and firing the inhaler can be done at the same time.



7. To clean, remove the aerosol can and rinse the plastic container in warm water. Dry thoroughly, then replace the aerosol can.

If you use more BECEZE CFC FREE than you should:

In event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use BECEZE CFC FREE:

If you forget to use a dose, use it as soon as you remember. Do not use a double or larger dose to make up for the forgotten individual doses. Continue to use the next inhalation at the usual time.

4. Possible side effects:

Not all side effects reported for BECEZE CFC FREE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BECEZE CFC FREE, please consult your healthcare provider for advice.

If any of the following happens, stop using BECEZE CFC FREE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash, hives (raised red bumps), severe itching and swelling of the eyes, face, lips and throat.
- These are all very serious side effects. If you have them, you have had a serious allergic reaction to BECEZE CFC FREE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty in breathing or wheezing directly after using BECEZE CFC FREE inhaler, as it may be a symptom of a condition called paradoxical bronchospasm.
- Wheezing, difficulty breathing, cough.
- Problems with your eyes or vision, blurred vision.
- Adrenal suppression, symptoms may include severe fatigue, weight loss and decreased appetite, darkening of your skin, low blood pressure, salt craving, low blood sugar, abdominal pain.
- Decreased bone density, symptoms may include decreased grip strength, weak and brittle fingernails, cramps, muscle aches, bone pain and height loss.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent occurrence:
• Thrush in your mouth or throat.

• Hoarseness.

• Unknown occurrence:

• Unintentional movements, sleep disorders, anxiety, depression, aggression and behavioural disorders.

• Headache.

• Nausea.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BECEZE CFC FREE.

5. How to store BECEZE CFC FREE

• Store at or below 25 °C.

• Avoid storage in direct sunlight or heat.

• Do not refrigerate.

• STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

• WARNING: This canister is pressurised. Do not puncture, break or burn the canister, even if it is apparently empty.

6. Contents of the pack and other information

What BECEZE CFC FREE contains:

The active substance is beklometasondipropionate.

BECEZE 50 CFC FREE contains 50 µg beklometasondipropionate per metered dose inhalation.

BECEZE 100 CFC FREE contains 100,0 µg beklometasondipropionate per metered dose inhalation.

BECEZE 250 CFC FREE contains 250,0 µg beklometasondipropionate per metered dose inhalation.

The other ingredients are anhydrous ethanol and hydrofluoroolethane.

What BECEZE CFC FREE looks like and contents of the pack:

Aerosol for inhalation supplied in a pressurised aluminium container. There should be no external damage, corrosion or leakage.

The container is a seamless aluminium canister with metered dispensing valve crimped in place.

Each canister of BECEZE CFC FREE provides 200 metered inhalations.

Holder of certificate of registration and manufacturer:

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park,

400 16th Road, Randjespark, Midrand 1685

South Africa

Tel: +27 (0) 11 848 3050

This leaflet was last revised:

04 April 2022

Registration number:

BECEZE 50 CFC FREE: 36/21.5.1/0192

BECEZE 100 CFC FREE: 36/21.5.1/0193

BECEZE 250 CFC FREE: 36/21.5.1/0194

Date of registration:

08 April 2005

Botsvana:

Reg. No. BOT1402641 S2

PIL 360192/3/4-1

BECEZE CFC FREE PATIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

S3

BECEZE 50 CFC FREE inhaleerdeer onder druk, oplossing
BECEZE 100 CFC FREE inhaleerdeer onder druk, oplossing
BECEZE 250 CFC FREE inhaleerdeer onder druk, oplossing
Beklometasondipropionate

Lees hierdie blad noukeurig deur voordat u begin om BECEZE CFC FREE te gebruik.
1. Hou hierdie blad. Dit mag nie wegstaan dat u dit weer moet lees.

- As u nog enige vroeë weet moet u asseblief vir u dokter, apoteker, verpleegkundige of ander gesondheidsoorgeskafferaar vra.
- BECEZE CFC FREE is vir u persoonlik voorgeskreif en moet nie u medisyne met ander mense deel nie. Denk dat hulle skakal, selfs al hulle simptome dieselfe is s'n.

Wat in hierdie blad is:

1. Wat BECEZE CFC FREE is en waaroor dit gebruik word

2. Wat u moet weet voordat u BECEZE CFC FREE gebruik

3. Hoe om BECEZE CFC FREE te gebruik

4. Moontlike newe-effekte

5. Hoe om BECEZE CFC FREE bewaar

6. Inhoud van die pak en ander inligting

1. Wat BECEZE CFC FREE is en waaroor dit gebruik word

Moenie BECEZE CFC FREE gebruik nie:

- as u hypersensitie (allergie) vir beklometasondip