Approved Patient Information Leaflet for 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

Beclometasone dipropionate

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 health care 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

1. What BECEZE CFC FREE is and what it is used for

BECEZE CFC FREE contains beclometasone dipropionate, 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 inadequately 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 beclometasone dipropionate 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 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 getting better, you feel generally unwell, you develop a rash, eczema or a runny nose 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 other 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 health care 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 health care provider if you are using medicine where you should avoid the use of alcohol. These medicines include 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 health care 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 of four 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 beclometasone dipropionate 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.

1. Remove the cap from the inhaler. Make sure the mouthpiece is clean and free from fluff and dirt.



2. Holding the inhaler upright, with your thumb on the base and your first finger on the top of the can. Now shake the inhaler vigorously up and down.



3. Breathe out fully to empty the lungs, then place the mouthpiece firmly between the lips.



4. Now breathe in slowly and deeply. At the same time, press the aerosol with your first finger to fire the aerosol and release beclometasone dipropionate.



5. Remove the inhaler from your mouth and hold your breath for 10 seconds, or as long as possible.



6. If more than one puff is required, wait at least one minute and repeat the procedure from step 2. Replace the cap.

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

4. Possible side effects

BECEZE CFC FREE can have 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 health care 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.
- Slow growth in children and adolescents.
- 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.
- Throat irritation.

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.
- Protect from freezing.
- 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 beclometasone dipropionate.

BECEZE 50 CFC FREE contains 50 µg beclometasone dipropionate per metered dose inhalation.

BECEZE 100 CFC FREE contains 100 µg beclometasone dipropionate per metered dose inhalation.

BECEZE 250 CFC FREE contains 250 µg beclometasone dipropionate per metered dose inhalation.

The other ingredients are anhydrous ethanol and hydrofluoroalkane.

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.

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

Holder of certificate of registration and manufacturer:

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