

FLOHALE INHALER CFC FREE

Fluticasone propionate (125mcg/actuation)

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What FLOHALE INHALER is used for

It is used to reduce symptoms and worsening of asthma if you are previously treated with bronchodilator (a medicine that helps to widen the airways) alone or with other preventive therapy. In adults, it is used in preventive management for mild, moderate and severe asthma. It is indicated in children who requires preventive medication including those not controlled on currently available preventive medication

How FLOHALE INHALER works

Flohale Inhaler belongs to a group of medicines called corticosteroids. It works by reducing swelling and irritation in the lungs. It has what is called an 'anti-inflammatory action'.

Before you use FLOHALE INHALER

-When you must not use it

Do not use FLOHALE INHALER if you are allergic (hypersensitive) to:

- Fluticasone propionate or any other ingredients listed at the end of this leaflet.

-Before you start to use it

Check with your doctor or pharmacist before using your medicine if:

- You have ever been treated for tuberculosis (TB).
- You have diabetes
- You have infection
- You are using FLOHALE INHALER at the same time as taking steroid tablets. Also, if you have just finished taking steroid tablets. In both cases, you

should carry a steroid warning card until your doctor tells you not to carry one. If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using FLOHALE INHALER.

Pregnancy and Lactation

Please tell your doctor if you are pregnant or trying to be pregnant or breastfeeding. Your doctor will decide depending on the expected benefits and risks.

-Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go into hospital.

Tell your doctor or pharmacist if you are taking any of the following:

- a type of antiviral medicine known as a protease inhibitor (such as ritonavir)
- medicines used to treat fungal infections (such as ketoconazole or itraconazole).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using FLOHALE INHALER

How to use FLOHALE INHALER

-How much to use it

Your doctor will have decided which strength you need. Always use FLOHALE INHALER exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

The medicine in FLOHALE INHALER should be inhaled using an inhaler. Make sure that you have one and can use it properly.

- Your inhaler technique should be checked regularly. During inhalation, you should sit or stand.
- If you are on higher doses (above 1,000 micrograms daily) you should take your medicine via the spacer device to help reduce side-effects in the mouth and throat. Your doctor, nurse or pharmacist will be able to advise you about this.

It takes a few days for this medicine to work and it is very important that you use it regularly

Adults and Children over 16 years of age

Mild asthma

-The usual starting dose is 100 micrograms twice a day.

Moderate to severe asthma

-The usual starting dose is 250 to 500 micrograms twice a day.

-The maximum dose should be 1000 micrograms twice a day.

Children 4 years of age and over
50 to 200 mg twice daily.

It should not be used for children under 4 years. The dose should be titrated down to the lowest dose at which effective control of asthma is maintained.

How long to use it

Do not stop treatment even if you feel better unless told to do so by your doctor. If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

-If you forget to use it

If you forget to use FLOHALE INHALER

- Take the next dose when it is due.
- Do not take a double dose to make up for the forgotten dose.

-If you use too much (overdose)

If you use more than you should, talk to your doctor as soon as possible. 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. Effect of overdose may cause suppression of adrenal function and acute adrenal crisis. Children aged < 16 years taking higher than 100mcg/day may be at particular risk. Presenting symptoms are typically vague and may include reduced appetite, abdominal pain, weight loss, tiredness, headache, nausea, and vomiting, decreased level of consciousness, low blood sugar, and seizures.

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While you are using FLOHALE INHALER

-Things you must do

Talk to your doctor as soon as possible if:

- after 7 days of using FLOHALE INHALER your shortness of breath or wheezing does not get better, or gets worse.
- It is important that your steroid is not stopped suddenly as this could make your asthma worse and could also cause problems with the body's hormones.

-Things you must not do

Individuals who have been on high doses of steroids, including FLOHALE INHALER for a long time, must not stop taking their medicine suddenly without talking to their doctor.

-Things to be careful of

- It is recommended that children being treated with steroids, including FLOHALE INHALER have their height checked regularly by their doctor.
 - If you are using high doses of an inhaled steroid for a long time you may sometimes need extra steroids for example during stressful circumstances.
 - FLOHALE INHALER cannot be used for treating sudden breathing difficulties. It is advised to have a short-acting bronchodilator (a medicine that helps to widen the airways) such rescue medication available
 - If you are having severe asthma, you will require regular medical examinations to check on the lungs.
 - If you are using more inhalations of bronchodilator than usual or the bronchodilator inhalation becomes less effective, you need to visit your doctor and your doctor may either increase the number of inhalations of FLOHALE INHALER or steroid tablet
- The replacement of systemic corticosteroid with FLOHALE INHALER can be accompanied by signs of adrenal insufficiency. When transferred to FLOHALE INHALER careful attention must be given to individual previously treated for prolonged periods with systemic corticosteroids. This is particularly important in those individual who have

associated asthma or other clinical conditions, where too rapid a decrease in systemic corticosteroids may cause a severe exacerbations of symptoms. Replacement of systemic steroid treatment with Flohale inhaler sometimes unmasks allergies such as allergic rhinitis or eczema. These allergies should be treated with antihistamine and/or topical preparations, including topical steroids.

Side effects

Like all medicines, FLOHALE INHALER can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist

If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away. You may need urgent medical treatment.

Side effects include:

Very common (affects more than 1 in 10 people)
-thrush in the mouth and throat

Common (affects less than 1 in 10 people)
-hoarseness of voice. Hoarseness and thrush in your mouth and throat can be reduced by rinsing your mouth with water after using the inhaler.

Very rare (affects less than 1 in 10,000 people)
-sleeping problems or feeling worried, over-excited and irritable. These effects are more likely to occur in children
-joint pain
-indigestion
-level of sugar (glucose) in your blood may be increased.
-Cushing's syndrome (abnormally high levels of a hormone called cortisol)
-Cushingoid features (eg. round face, weight gain)
-adrenal suppression
-growth retardation in children and adolescents
-decreased bone mineral density
-cataract (clouding of eye lens)
-glaucoma (increased pressure inside the eye)

-angioedema (swelling of deeper layers of the skin) mainly facial and oropharyngeal (middle part of the throat behind the mouth)
-respiratory symptoms such as shortness of breath or breathing difficulty
-anaphylactic reactions (severe, potentially life-threatening allergic reaction)

If your breathing or wheezing gets worse (paradoxical bronchospasm) immediately after dosing, Flohale Inhaler should be discontinued immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public --> Reporting Medicinal Problems / Side Effects / AEFI/ Vaccine Safety).

Storage and Disposal of FLOHALE INHALER

-Storage

-Store below 30°C. Do not freeze.

-Keep out of the reach and sight of children.

-Do not use FLOHALE INHALER 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.

-The metal canister is pressurised. Do not puncture, break or burn it even when apparently empty.

-Disposal

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.

Product description

- What it looks like

Flohale inhaler is a white homogenous suspension aerosol for inhalation, in propellant HFA-134a, supplied in a pressurized container. On visual

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examination there should be no sign of physical damage, or leakage.

- Ingredients

-Active ingredient: Fluticasone propionate

-Inactive ingredients: Ethanol, Lecithin and Tetrafluoroethane (HFA-134a)

-MAL Number: MAL10021809AZ

Manufacturer

Cipla Ltd.
L-139 to L-146
Verna Industrial Estate,
Goa 403 722
India

Product Registration Holder

Cipla Malaysia Sdn Bhd
Suite 1101, Amcorp Tower,
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Date of revision

20/09/2017

Serial Number

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How to use FLOHALE-125 INHALER (CFC FREE)

Instructions for use

Parts of the Inhaler



How to use your inhaler correctly testing your inhaler

Before using your Inhaler for the first time, or if it has not been used for a week or more, "test fire" it, i.e. release one puff into the air.



Using your Inhaler

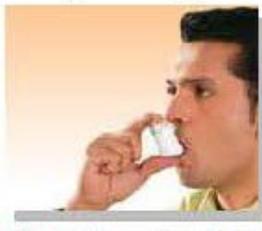
1. Remove the mouth piece cover and check that the mouthpiece is clean. Hold the Inhaler upright as shown, with your thumb on the base. Place either one or two fingers on top of the canister.



2. Breathe out gently, through your mouth.



3. Place the mouth piece of the inhaler in your mouth between your teeth and close your lips around it (Do not bite it). Start breathing in slowly through your mouth. As you breathe in, press down the canister to release one dose while continuing to breathe in steadily and deeply.



4. Remove the Inhaler from your mouth and hold your breath for 10 seconds, or for as long it is comfortable. Breathe out slowly.



5. If another dose is required wait for at least one minute. Repeat steps 2 to 4. After use, replace the mouthpiece cover. Rinse mouth after each use



Important:

Do not rush steps 3 and 4. It is important that you start to breathe in as slowly as possible just before releasing the dose. Practise in front of the mirror for the first few times.



the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.

Cleaning

It is essential to keep the plastic mouthpiece clean, to ensure proper functioning of the inhaler. Clean your inhaler at least once a week as follows:

1. Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.



2. Immerse the plastic body and the mouthpiece cover in warm water. Do not put the metal canister in water.



3. Next, rinse the plastic body and mouthpiece cover under running tap water.



4. Shake well to remove excess water. Leave to dry. Avoid the use of heat.

5. When the plastic body is dry, replace the canister and the mouthpiece cover correctly.

Warning

If the recommended dose does not provide the desired effect, consult your doctor. It is dangerous to exceed the recommended dose. The metal canister is pressurized. Do not puncture or burn it even when empty. Keep away from eyes. Keep away from children.

If you see "mist" coming from the top of