

Package leaflet – Information for the user

Kelhale 50 micrograms per actuation pressurised inhalation solution

Kelhale 100 micrograms per actuation pressurised inhalation solution

Beclometasone dipropionate

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Kelhale is and what it is used for

Kelhale contains beclometasone dipropionate, which is one of a group of medicines known as corticosteroids.

Kelhale is used to prevent the symptoms of mild, moderate, or severe asthma, in adults over 18 years of age who require regular treatment.

How your medicine works

- Kelhale works deep in your lungs to make breathing easier by reducing the inflammation, swelling and irritation in the airways. This type of medicine is known as a ‘preventer’. It needs to be taken regularly every day, even if you have no symptoms.
- This inhaler will not give immediate relief of wheezing or breathlessness during a sudden asthma attack. You will need to use a ‘reliever’ inhaler, which contains a different medicine. You should still continue to use this inhaler.

2. What you need to know before you take Kelhale

Do not take Kelhale if you:

- are allergic to beclometasone dipropionate or any of the other ingredients of this medicine (listed in section 6)
- are allergic to other similar inhalers.
- are suffering from 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 or pharmacist before you start to take this medicine if:

- you are suffering from tuberculosis (TB) now or have you suffered from it in the past.
- you must avoid alcohol for any reason.
- 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. Your doctor may need to increase the dose of your steroid inhaler or give you a course of steroid tablets, or change your treatment altogether. If you have had an infection in your chest your doctor may prescribe a course of antibiotics.
- 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.

Important points to remember while you are using this medicine:

- Your doctor may prescribe this inhaler to replace steroid tablets, which may mean for a short time you have to take both medicines. It is important to follow your doctor's advice. Whilst you are reducing the number of steroid tablets that you take you may feel generally unwell even though you can breathe as well as normal or better. If you have other allergies you may find that stopping your steroid tablets makes them worse. If this happens keep using your inhaler and tell your doctor.
- 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.
- There may be times when you need to take steroid tablets as well as using your inhaler, for example if you have worsening asthma attacks, you get a chest infection or you need an operation. Your doctor may give you a small supply of steroid tablets to be taken in these situations; if he/she does you will be given full instructions on how and when to take them. Contact your doctor immediately if you think that you need to take steroid tablets, even if you have your own supply.
- You should have been given a steroid card with this inhaler, if you have not, please ask your pharmacist for one. Make sure you carry your steroid card with you at all times until your doctor decides that it is no longer necessary.
- Visit your doctor regularly for a review of your condition.
- If you have to go into hospital, remember to take all your inhalers and other medicines including those bought without prescription with you.
- Contact your doctor if you experience blurred vision or other visual disturbances

Children and adolescents

Kelhale is not intended for children below 18 years of age.

Other medicines and Kelhale

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular tell your doctor if you are taking:

- Disulfiram
- Metronidazole

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

Pregnancy, breast-feeding and fertility

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

Kelhale is not known to affect your ability to drive or operate machinery.

Kelhale contains ethanol

Kelhale contains a small amount of alcohol.

3. How to take Kelhale

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

There are two strengths of Kelhale available and your doctor will have chosen the strength which best suits your condition.

This inhaler has a softer feel and a different taste than other inhalers you may have used before. This inhaler is an extra fine aerosol which results in more of each dose being delivered to your lungs. Your doctor may, therefore, prescribe a lower dose of this inhaler than your previously used inhaler.

Even when your doctor has prescribed a lower dose you may find that the number of puffs you are asked to take from this inhaler is the same as from your previous inhaler; this is because this inhaler may be a lower strength product (which means that each puff of this inhaler contains less beclometasone dipropionate than your old inhaler).

DO NOT take more puffs than your doctor has told you to.

In some circumstances, your doctor may prescribe more than the usual number of puffs. The usual number of puffs to take is:

Kelhale 50 micrograms inhaler

Adults (including the elderly)

Mild asthma

The starting dose is one puff twice a day. This may be increased up to two puffs twice a day.

Moderate asthma

The starting dose is two puffs twice a day. This may be increased up to four puffs twice a day.

Severe asthma

The starting dose is four puffs twice a day. This may be increased up to eight puffs twice a day. The maximum dose is a total of sixteen puffs a day.

Kelhale 100 micrograms inhaler**Adults (including the elderly)****Mild Asthma**

The Kelhale 100 micrograms inhaler is not suitable for the starting dose. It is suitable for an increased dose of one puff twice a day.

Moderate Asthma

The starting dose is one puff twice a day. This may be increased to two puffs twice a day.

Severe asthma

The starting dose is two puffs twice a day. This may be increased up to four puffs twice a day. The maximum dose is a total of eight puffs a day.

Children and adolescents under 18 years

Kelhale is not intended for use in children under 18 years.

What to do if you think your treatment is not working

If you think your usual treatment is not working, for example your symptoms are not getting better, or are getting worse, or you need to use more puffs from your reliever inhaler, or if your reliever inhaler does not seem to be working as well as usual, or your peak flow falls, please tell your doctor. Your asthma may be getting worse.

If you use more Kelhale than you should

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 accidentally take more puffs than recommended, please tell your doctor.

If you forget to use Kelhale

If you forget to use this inhaler at your usual time, take your recommended number of puffs as soon as you remember unless it is nearly time to use your inhaler again. DO NOT take a double dose to make up for a forgotten dose. Then continue to use your inhaler regularly at the correct time, as prescribed by your doctor.

If you stop using Kelhale

This inhaler must be used regularly, even when you feel well. You must not stop using your inhaler unless your doctor tells you to.

Ask your doctor for a prescription for a replacement inhaler before this one is empty.

If your doctor decides to stop treatment, return the inhaler to your doctor or pharmacist for safe disposal.

Using your Kelhale inhaler**Testing your Inhaler**

When you use the inhaler for the first time you should test if it works properly. Also do this if you have not used the inhaler for two weeks or more.

1. Remove the mouthpiece cover by gently pressing the sides with your thumb and index finger.
2. Point the mouthpiece away from you and press the canister twice (once at a time) to release two puffs into the air.

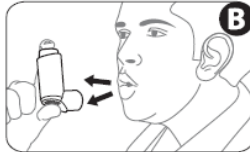
How to use your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

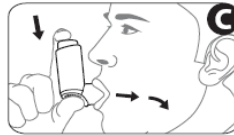
1. You should either stand up or sit upright when using your inhaler
2. Remove the mouthpiece cover. Check inside and outside to make sure that the mouthpiece is clean and free of objects (figure A).



3. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out for as long as is comfortable (figure B. Do not breathe in again yet).



4. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite (figure C).



5. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply (figure C).
6. Hold your breath, take the inhaler from the mouth and your finger from top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable (figure D).



7. If your doctor has told you to take two puffs, wait about a minute before you take another puff by repeating steps 3 to 7.
8. After using your inhaler always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.
9. There is an indicator at the back of the Inhaler which tells you how many doses are left. The dose indicator will show the approximate no of doses remaining in the inhaler.
10. A new inhaler first shows “200” in the dose indicator window.

Image:



11. As you use the inhaler the dose indicator will typically move towards next decreasing number.
12. Count for number of sprays remaining in the container will be displayed after every 20 actuation.
13. You should get a replacement when the indicator displays the number ‘40’.

Image:



14. Stop using the inhaler, when the indicator displays '0' as the correct amount of medication in each inhalation cannot be assured after counter reads 0, even though the canister is not completely empty and will continue to operate.

Image:



15. The canister should be discarded when the indicator displays '0'.
16. Never try to alter the numbers on the indicator or detach the indicator from the actuator. The indicator cannot be reset and is permanently attached to the actuator.

The mouthpiece has been designed specially for use with this product only. Do not use any other mouthpiece with the product and do not use the mouthpiece provided here with any other product.

Practice in front of a mirror the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth you should start again.

People with weak hands 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. Your doctor, nurse or pharmacist will be able to advise you.

The inhaler can be used with a device called Aerochamber Plus spacer. This may be useful for people who find it difficult to synchronise breathing in and inhaler actuation.

Please talk to your doctor if you have difficulties to use the Kelhale.

How to tell when your Kelhale device is empty

Your inhaler comes with a dose indicator. Stop using the inhaler when the indicator displays '0'.

Cleaning instructions

For normal hygiene, the mouthpiece of your inhaler should be cleaned weekly with a clean, dry tissue or cloth. You should also rinse your mouth with water after using your inhaler.

Do not wash or put any part of your inhaler in water.

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

4. Possible side effects

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

If immediately after taking a puff of this inhaler, you feel wheezy or tight chested do not take any more puffs. Use your reliever inhaler to help your breathing and contact your doctor immediately.

Stop using your inhaler and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, eye, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Keep using your inhaler but see your doctor as soon as possible if you become unwell, particularly with any of the following:

- abdominal pain
- weakness
- vomiting

This is especially important if you have been exposed to other stress such as other illness, surgery, or infection.

The following side effects may also occur in patients taking beclomethasone dipropionate. If you experience any of these effects, keep using your inhaler but see your doctor if they last for a while or they are worrying you:

Other side effects:

Common (may affect **up to 1 in 10** people):

- a sore mouth or thrush (white spots in your mouth and throat). These are less likely if you rinse your mouth out with water after using your inhaler. If you get thrush your doctor may recommend a medicine to treat you
- hoarseness
- difficulty in swallowing accompanied by earache and swollen glands, sore throat (pharyngitis)
- change in taste

Uncommon (may affect **up to 1 in 100** people):

- headache
- feeling dizzy or faint
- tremor (shaking)
- difficulty in breathing increase in wheezing, shortness of breath and cough (bronchospasm)
- feeling sick
- hives (urticaria)
- rash
- itching (pruritus)
- redness of the skin (erythema)
- blurred vision

Very rare (may affect **up to 1 in 10000** people):

- decrease in function of the adrenal gland, which is responsible for producing some hormones that control your body.
- clouding of the lens of the eye (cataract) resulting in blurred vision
- loss of vision due to abnormally high pressure in the eye may occur.
- bone thinning
- rounded face (full moon) (Cushing's syndrome)

Not known (frequency cannot be estimated from the available data):

- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <https://yellowcard.mhra.gov.uk/> 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 Kelhale

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer packaging after EXP. The expiry date refers to the last day of the month.

Do not store above 25°C. Avoid storage in direct sunlight or heat. Protect from frost. You can use your inhaler at temperatures as low as -10°C.

The canister is pressurised and should not be punctured or burnt even if it seems empty.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kelhale contains

- The active substances is beclometasone dipropionate.
 - Kelhale 50 micrograms inhaler: One metered dose (ex-valve) contains 50 micrograms of beclometasone dipropionate
 - Kelhale 100 micrograms inhaler: One metered dose (ex-valve) contains 100 micrograms of beclometasone dipropionate
- The other ingredients are HFA-134a (norflurane) and ethanol.

What Kelhale looks like and contents of the pack

Kelhale is supplied as a colourless solution in an aluminium container fitted with a suitable metering valve and a plastic actuator made up of polypropylene with a dose indicator. Each inhaler delivers 200 actuations.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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