

PACKAGE LEAFLET: INFORMATION FOR USER

PREVENTER

Clenil® Modulite® 50 micrograms per metered dose pressurised inhalation solution
Clenil® Modulite® 100 micrograms per metered dose pressurised inhalation solution
Clenil® Modulite® 200 micrograms per metered dose pressurised inhalation solution
Clenil® Modulite® 250 micrograms per metered dose 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 Clenil Modulite is and what it is used for**
- 2. What you need to know before you use Clenil Modulite**
- 3. How to use Clenil Modulite**
- 4. Possible side effects**
- 5. How to store Clenil Modulite**
- 6. Contents of the pack and other information**

1. What Clenil Modulite is and what it is used for

Clenil Modulite is a pressurised inhalation solution used to help **prevent** the symptoms of mild, moderate or severe 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 Clenil Modulite

Do not use Clenil Modulite:

- 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 Clenil Modulite if any of the following applies to you:

- you are being, or have ever been, treated for tuberculosis (TB)
- you must avoid alcohol because you suffer from any of the following diseases or conditions: liver disease, alcoholism, epilepsy, any brain injury or disease. Each puff of your inhaler contains less than 9 mg of alcohol.
- 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 may give you a course of steroid tablets or change your treatment altogether. If you have 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.

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 Clenil Modulite 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 Clenil Modulite:

Before starting treatment, please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Remember to take these medicines and your inhalers with you if you have to go into hospital.

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

Clenil Modulite contains alcohol:

This medicine contains less than 9 mg of alcohol (ethanol) in each actuation, which is equivalent to 0.88 mg/kg per dose in adults and 1,54 mg/kg per dose in children. The maximum amount of ethanol per dose in this medicine is equivalent to less than 2 ml of wine or beer. The small amount of alcohol in this medicine will not have any noticeable effects.

However, you **must** tell your doctor if you are taking any of the following:

- disulfiram, to treat long-lasting alcoholism
- metronidazole, to treat bacterial infections

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:

Clenil Modulite is not likely to affect you being able to drive or use any tools or machines.

3. How to use Clenil Modulite

Always use this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Clenil Modulite is available in 4 different strengths and must only be breathed into your lungs through your inhaler. "Instructions for use" of your inhaler are given after the dosage section.

It takes a few days for Clenil Modulite 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 Clenil Modulite 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. Your doctor will prescribe the lowest dose of Clenil Modulite that will control your symptoms. The label on your inhaler will tell you how much to take and how often.

A spacer device should always be used when:

- adults, the elderly and adolescents are taking total daily doses of Clenil Modulite of 1,000 micrograms or more.

Adults, including the elderly, and adolescents over the age of 12 years

- For mild asthma, the usual dose is 200 micrograms a day in divided doses. Your doctor may decide to increase your dose up to 600 micrograms a day.
- For moderate asthma, the usual dose is 600 micrograms a day in divided doses. Your doctor may decide to increase your dose up to 1000 micrograms a day.
- For severe asthma the usual dose is 1000 micrograms a day in divided doses. Your doctor may decide to increase your dose up to 2000 micrograms a day.

Children over the age of 4 years

- The usual dose is up to 400 micrograms a day, in divided doses.

If you use more Clenil Modulite 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 Clenil Modulite:

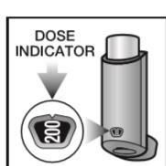
If you forget to use your inhaler, miss out your forgotten dose and take the next dose when it is due. Do not take more puffs than you were told to take.

Instructions for use:

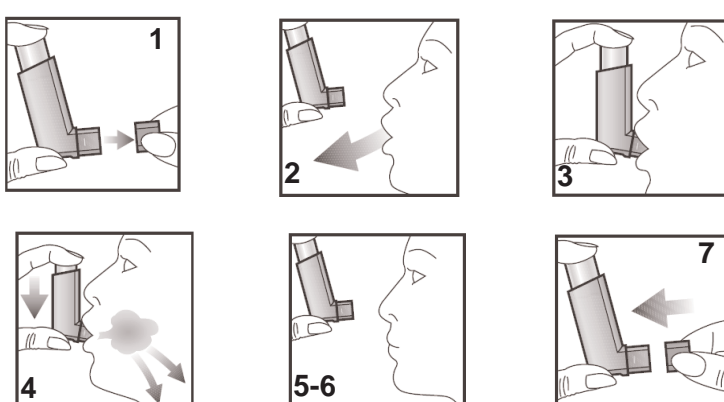
It is important that you know how to use your inhaler properly. Your doctor, nurse or pharmacist will show you how to use your inhaler correctly and will check regularly that you are using your inhaler correctly. You must follow their instructions carefully, so that you know **how, when and how many** 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.



This medicine is contained in a pressurised canister in a plastic casing with a mouthpiece. There is a dose indicator on the back of the inhaler which tells you how many puffs are left:



Each time you press the canister, the dose indicator rotates by a small amount. The number of puffs remaining is displayed in intervals of 20. Take care not to drop the inhaler as this may cause the dose indicator to count down.



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. If you are testing your inhaler for the first time, 200 should be displayed on the dose indicator.

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, snap into position and check the dose indicator.**

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.

When to replace your inhaler

When the indicator shows 20 doses left, you should request a new inhaler from your doctor. This will ensure you have a replacement in good time. When the '0' appears centrally in the window the medicine has run out and you should discard the inhaler. Your inhaler may feel like there are still some contents remaining, but any remaining puffs may not contain enough medicine and should not be used.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, Clenil 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 need to use a spacer device. Ask your doctor, pharmacist or a nurse about this device.

However, a spacer device must always be used if:

- you are an adult, elderly or an adolescent and are taking total daily doses of Clenil Modulite of 1,000 micrograms or more.

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

Cleaning your inhaler:

You should clean your inhaler once a week. When cleaning, do not remove the canister can from the actuator and do not use water or other liquids to clean your inhaler. To clean your inhaler:

1. Remove the protective cap from the mouthpiece by pulling it away from your inhaler.
2. Use a clean cotton swab to clean the small circular opening where the medicine sprays out of the canister. Gently twist the swab in a circular motion to take off any medicine.
3. Replace the mouthpiece cover.

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

4. Possible side effects

Like all medicines, Clenil Modulite can cause side effects, although not everybody gets them.

If your breathing or wheezing gets worse straight after using your inhaler, stop using Clenil Modulite 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 Clenil Modulite in the lowest dose possible to control your asthma.

Very common (affecting more than 1 in 10 people):

- thrush in the mouth and throat. 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 Clenil Modulite. Brushing your teeth or thoroughly rinsing your mouth with water immediately after each dose may help prevent thrush.

Common (affecting less than 1 in 10 people):

- hoarseness, sore throat. Using a spacer device or rinsing your mouth with water immediately after using your inhaler may help prevent this.

Uncommon (affecting less than 1 in 100 people):

- hypersensitivity reactions such as rashes, itching, redness of the skin, nettle rash or hives

Very rare (affecting less than 1 in 10,000 people):

- hypersensitivity reactions such as swelling of the face, eyes, lips and throat, caused by a build up of fluid in the body tissues
- wheezing with a shortness of breath
- anxiety
- sleep disorder
- abnormal behaviour (over excited and irritable), especially in children
- problems with how your adrenal gland works
- increased pressure in the eyes
- cataract
- 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 Clenil Modulite at high doses over a long period of time.
- Cushing's syndrome caused by excess amounts of steroid hormones in the body, resulting in weight gain, reddening of the face and neck, excess growth of facial and body hair, raised blood pressure, loss of mineral from the bones, raised blood glucose levels and developing a round "moon" face.

Frequency not known:

- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
- headaches
- nausea (feeling sick)
- blurred vision

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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:

HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clenil Modulite

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

- Do not use Clenil Modulite 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 refrigerate or freeze your inhaler.
- 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. **Never** 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 Clenil Modulite 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 norflurane (HFA 134-a).

What Clenil Modulite looks like and content of the pack

Clenil Modulite is a pressurised inhalation solution contained in an aluminum can with plastic actuator and protective cap. Each canister contains 200 puffs.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder of Clenil Modulite is Chiesi Farmaceutici S.p.A., 26/A Via Palermo, 43122 Parma, Italy.

The manufacturer of Clenil Modulite is Chiesi Farmaceutici S.p.A., 96 via S. Leonardo, 43122 Parma, Italy or Chiesi S.A.S, 2 rue des Docteurs Alberto et Paolo Chiesi, 41260 La Chaussee Saint-Victor, France

Is this leaflet hard to see or read? Phone 0161 488 5555 for help

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