Chiesi

PACKAGE LEAFLET: INFORMATION FOR USER

PREVENTER

Clenil® Modulite® 50 micrograms per actuation pressurised inhalation solution
Clenil® Modulite® 100 micrograms per actuation pressurised inhalation solution
Clenil® Modulite® 200 micrograms per actuation pressurised inhalation solution
Clenil® Modulite® 250 micrograms per actuation 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 pressurised inhalation solution is 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 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 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.

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

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).

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.

Clenil Modulite contains alcohol:
This medicine contains less than 9 mg of alcohol (ethanol) in each actuation, which at the maximum 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.

3.How to use Clenil Modulite

Clenil Modulite is available in 4 different strengths. Your doctor will have decided which strength you need. Clenil Modulite 200 and Clenil Modulite 250 are not suitable for children.

Always use your inhaler exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Instructions for using your inhaler are given after the dosage section.
It takes a few days for your inhaler 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.
It may be higher than the doses given below. Your doctor will prescribe the lowest dose of Clenil Modulite that will control your symptoms.

A device called a Volumatic spacer should **always** be used when:
- adults, the elderly and adolescents 16 years of age and older are taking total daily doses of Clenil Modulite of 1,000 micrograms or more,
- when Clenil Modulite is used in children and adolescents 15 years of age and under whatever dose has been prescribed.

Clenil Modulite 50 micrograms
The common starting dose is:
Adults and the elderly: 200 micrograms (4 puffs) twice a day
Children: 100 micrograms (2 puffs) twice a day

Usually the most you would take in a day is:
Adults and the elderly: 800 micrograms (16 puffs)
Children: 400 micrograms (8 puffs)

The total daily dose may be divided into 2, 3 or 4 doses per day.

Clenil Modulite 100 micrograms
The common starting dose is:
Adults and the elderly: 200 micrograms (2 puffs) twice a day
Children: 100 micrograms (one puff) twice a day

Usually the most you would take in a day is:
Adults and the elderly: 800 micrograms (8 puffs)
Children: 400 micrograms (4 puffs)

The total daily dose may be divided into 2, 3 or 4 doses per day.

Clenil Modulite 200 micrograms
The common starting dose is:
Adults and the elderly only: 200 micrograms (1 puff) twice a day

Usually the most you would take in a day is: 800 micrograms (4 puffs)

The total daily dose may be divided into 2, 3 or 4 doses per day.
This product strength is not suitable for children

Clenil Modulite 250 micrograms
The common starting dose is:
Adults and the elderly only: 500 micrograms (2 puffs) twice a day

Usually the most you would take in a day is: 2,000 micrograms (8 puffs)

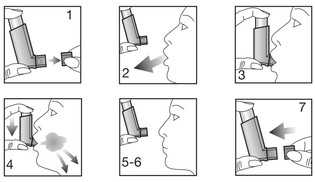
The total daily dose may be divided into 2, 3 or 4 doses per day.
This product strength is not suitable for children

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 take your Clenil Modulite, 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.



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.

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 and snap into position.**

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.

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 use the Volumatic spacer device. Ask your doctor, pharmacist or a nurse about this device.
However, the Volumatic spacer device must always be used if:
- you are an adult, elderly or an adolescent 16 years of age and older and are taking total daily doses of Clenil Modulite of 1,000 micrograms or more,

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- Clenil Modulite is used in children and adolescents 15 years of age and younger, whatever dose has been prescribed.

Young children may find it difficult to use the inhaler properly and will require help. Using the inhaler with the Volumatic spacer device with a face mask may help in children under 5 years. **Tell your doctor, nurse or pharmacist if you have any difficulties**.

Cleaning your inhaler:
It is important to clean your inhaler at least once a week, to stop it blocking up.
- Pull the metal canister out of the plastic case of the inhaler and remove the mouthpiece cover.
- Rinse the plastic case and the mouthpiece cover in warm water. If you use a mild liquid detergent, rinse carefully with clean water before drying. Do not put the metal canister into water.
- Leave to dry thoroughly in a warm place. Avoid excessive heat.
- Replace the canister and mouthpiece cover.

It is important that you also read the Package leaflet which is supplied with your Volumatic spacer device and that you follow the instructions on how to use the Volumatic 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 you notice an immediate increase in wheezing, shortness of breath and cough 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 (may affect 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 (may affect up to 1 in 10 people):

- Hoarse voice or a sore throat or tongue. Using a Volumatic spacer device or rinsing your mouth with water immediately after using your inhaler may help prevent this.

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

- Allergic reactions including skin rashes, hives, itching or redness.

Very rare (may affect up to 1 in 10,000 people):

- Swelling of the face, eyes, lips and throat.
- Changes to the normal production of the steroids in the body, particularly after treatment with Clenil Modulite at high doses over a long period of time.
- 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.
- A decrease in bone mineral density (thinning and weakening of the bones) and eye problems which include the formation of cataracts and glaucoma (increased pressure in the eye).
- If you become unwell or develop symptoms such as loss of appetite, abdominal pain, weight loss, tiredness, nausea (feeling sick), vomiting (being sick), feeling faint, sweating and possible convulsions (fits), you should consult your doctor. This is particularly important if you have been exposed to stress such as surgery, infection, an acute attack of asthma, or other serious illness. Your doctor may carry out blood test from time to time to monitor the levels of steroids in your body.

Unknown (frequency cannot be estimated from the available data):

- 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 the YellowCard Scheme at www.mhra.gov.uk/yellowcard 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 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 store the inhaler above 30°C. Protect from frost and direct sunlight.
- 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 the propellant norflurane (HFC-134a).

Clenil Modulite 50:
This medicine contains fluorinated greenhouse gases. Each inhaler contains 12.130 g of norflurane (HFC-134a) corresponding to 0.017 tonne CO2 equivalent (global warming potential GWP = 1430).

Clenil Modulite 100:
This medicine contains fluorinated greenhouse gases. Each inhaler contains 12.130 g of norflurane (HFC-134a) corresponding to 0.017 tonne CO2 equivalent (global warming potential GWP = 1430).

Clenil Modulite 200:
This medicine contains fluorinated greenhouse gases. Each inhaler contains 11.950 g of norflurane (HFC-134a) corresponding to 0.017 tonne CO2 equivalent (global warming potential GWP = 1430).

Clenil Modulite 250:
This medicine contains fluorinated greenhouse gases. Each inhaler contains 11.780 g of norflurane (HFC-134a) corresponding to 0.017 tonne CO2 equivalent (global warming potential GWP = 1430).

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 Limited, 333 Styal Road, Manchester, M22 5LG, United Kingdom.
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.

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