CLENIL® 250 mcg Inhalations Chiesi
Beclometasone

**Composition**
Each canister contains:
*Active ingredient*: beclometasone-17,21-dipropionate 50 mg (each actuation delivers 250 micrograms)
*Excipients*: HFA 134a (norflurane), ethanol, glycerol.
Pressurised container providing 200 inhalations of 250 micrograms of beclometasone.
The product does not contain any substance damaging ozonosphere.

**Therapeutic indications**
Control of asthmatic disease development and of bronchostenotic conditions in those patients who do not obtain a satisfactory control of symptoms with the usual inhaled doses of beclometasone dipropionate.

**Contraindications**
Tubercular (active or quiescent) and local viral infections. Individual hypersensitivity to cortisonics.
Usually contraindicated in pregnancy and lactation (see Special warnings)

**Precautions for use**
Patients should be properly instructed about the correct use of the inhaler.
The management of treatment in patients already undergoing systemic corticotherapy, needs special precautions and a strict medical control since the reactivation of adrenal function, suppressed by the prolonged systemic corticosteroidal therapy, is slow. In any case, it is necessary that the disease be relatively stabilised by the systemic treatment. At the beginning, Clenil should be administered while continuing the systemic therapy; then, this should be gradually reduced checking the patient regularly (in particular, periodical tests of corticoadrenal function should be carried out) and modifying Clenil posology according to the results obtained. During periods of stress or of severe asthmatic attacks, patients undergoing this passage shall be supported by a supplemental treatment with systemic steroids.

Clenil is not effective in asthmatic attack in progress; on the contrary, it represents an essential treatment of the asthmatic disease, therefore it should be regularly taken at the prescribed doses and as long as the physician deems it as suitable.

Patients should be duly informed that the product contains small amounts of ethanol and glycerol. These quantities are negligible and do not constitute a risk for patients with the usually administered therapeutic doses. However, due to the presence of alcohol, the product should be cautiously used in patients suffering from hepatic pathologies, alcoholism (see also Interactions), epilepsy, cerebral pathologies.

**Interactions**
Clenil contains a small amount of ethanol. There is the theoretical potential for interaction in particularly sensitive patients taking disulfiram or metronidazole.

**Special warnings**
Clenil is not efficacious in asthma attacks in progress; on the contrary, it represents a fundamental treatment of the asthmatic disease: it should be regularly taken at the prescribed doses and as long as the physician deems it as suitable.
Pregnancy and lactation
In pregnant women the product should be administered in case of real need and under direct medical control. There is inadequate evidence of safety of beclometasone dipropionate or HFA 134a propellant in humans. Product administration during pregnancy and lactation should be only taken into consideration if the envisaged benefit for the mother outweighs the potential risks for the foetus.

Children born from mothers having received considerable doses of inhaled corticosteroids during pregnancy, should be carefully monitored in order to detect a possible hypoadrenalism.

Studies on the effects of the propellant HFA 134a on reproductive function and embryofetal development in animals did not point out clinically important adverse events. Therefore, the occurrence of adverse events in humans is unlikely.

Posology, method and frequency of administration
Adults: usually, 2 inhalations twice a day. Should it be deemed as more suitable, posology can be fractioned even into 1 inhalation 4 times daily. In case of need, therapy can be increased up to 2 inhalations 3-4 times a day.
Therapy with CLENIL should not be abruptly interrupted
Children: CLENIL 250 mcg is not suitable for pediatric use.

Undesirable effects
Occasionally, local mycotic infections (candidiasis) can appear in the oropharyngeal cavity, usually rapidly regressing after local antimycotic therapy and without interrupting the treatment. The occurrence of these mycotic infections can be reduced to the minimum by regularly rinsing the mouth after every application.
A few patients complained about hoarseness and dry mouth.

Systemic side effects are extremely improbable with the recommended doses; however, patients should be kept under strict control during prolonged treatments, in order to timely ascertain the possible occurrence of systemic diseases (osteoporosis, peptic ulcer, signs of secondary corticoadrenal insufficiency, such as hypotension and weight loss) and in order to avoid, in this latter event, very serious accidents due to acute hypoadrenalism. Inhalation of high doses (> 1500 mcg/die) for prolonged periods may cause adrenal suppression. As with other inhalation therapy paradoxical bronchospasm may occur.

The observance of the instructions contained in the package insert reduces the risk of undesirable effects.
It is important to promptly inform the physician or chemist about any undesirable effect, even if not reported in this leaflet.

Shelf life
See the expiry date reported on the box; this date is intended for the unopened and correctly stored product.
Attention: do not use the medicinal product when the indicated date is expired.

Precautions for storage
The pressurised container should not be pierced and should be protected from heating sources, even when apparently empty. It must neither be frozen nor exposed to direct sunlight. Store below 30°C.
Keep out of the reach of children
Last revision: March 2001
**CLENIL® 50 mcg Inhalations**  
*Chiesi*  
*Beclometasone*

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Pressurised canister providing 200 inhalations of 50 micrograms of beclometasone  
The product does not contain any substance damaging the ozonosphere.

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**Contraindications**  
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**Pregnancy and lactation**  
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Children born from mothers having received considerable doses of inhaled corticosteroids during pregnancy, should be carefully monitored in order to detect a possible hypoadrenalism.

Studies on the effects of the propellant HFA 134a on reproductive function and embryofoetal development in animals did not point out clinically important adverse events. Therefore, the occurrence of adverse events in humans is unlikely.

**Posology, method and frequency of administration**

*Adults:* the mean dose is of 2 inhalations (= 100 mcg of active ingredient) 4 times daily. In severe cases, it is advisable starting therapy with 3-4 inhalations (= 150-200 mcg of active ingredient) 4 times a day and adjust dosage according to the therapeutic response.

*Children aged under 12 years:* 1-2 inhalations (= 50-100 mcg of active ingredient) 2 to 4 times daily, according to the therapeutic response.

The maximum daily administration should not exceed 20 inhalations (1 mg) in adult patients.

It is important for patient to understand that Clenil is not a bronchodilating aerosol: it should be regularly used and not to obtain a rapid bronchospasm resolution.

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