Clenil® 250 mcg
Pressurised Inhalation Solution

beclomethasone dipropionate

COMPOSITION
Each container contains: **Active ingredient:** beclomethasone-17,21-dipropionate 50 mg (each actuation contains 250 micrograms). **Excipients:** HFA 134a (norflurane), ethanol, glycerol.

PHARMACEUTICAL FORM AND CONTENT
Pressurised inhalation solution.
Pressurised container sufficient for 200 inhalations of 250 micrograms of beclomethasone. The product does not contain ozone-depleting substances.

THERAPEUTIC INDICATIONS
Control of development of asthmatic disease and bronchostenosis conditions in patients who cannot obtain satisfactory control of symptoms with the usual doses of beclomethasone dipropionate by inhalation.

CONTRAINDICATIONS
Tubercular infections (active or quiescent) and local viral infections. Individual hypersensitivity to cortisone-based drugs. Usually contraindicated in pregnancy and lactation (see Special warnings)

PRECAUTIONS FOR USE
Patients should be instructed in the proper use of the inhaler. The management the treatment in patients already undergoing systemic corticotherapy needs special precautions and strict medical control since the reactivation of adrenal function, suppressed by prolonged systemic corticosteroid treatment, is slow. In any case, it is necessary for the disease to be relatively "stabilized" with the systemic treatment. At the beginning, CLENIL should be administered while continuing the systemic treatment; then, this should be gradually reduced checking the patient regularly (in particular, periodical tests of corticoadrenal function should be carried out) and modifying the CLENIL posology according to the results obtained. During periods of stress or severe asthmatic attacks, patients undergoing this change must be supported by a supplemental treatment with systemic steroids. Patients should be advised that the product contains small quantities 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. It is important that the posology of inhaled corticosteroids be reduced to the lowest dose effective for asthma control and be regularly adjusted. In fact, possible systemic effects, such as adrenal suppression, even acute, growth retardation in children and adolescents, reduced bone mineral density, cataract and glaucoma can occur following long-term inhaled corticosteroid treatment at high doses. Very rare cases of acute adrenal crisis have occurred in children exposed to doses higher than those recommended (about 1000 mcg/day) for prolonged periods (several months or years). Symptoms of adrenal insufficiency are initially aspecific and include anorexia, abdominal pain, weight loss, tiredness, headache, nausea and vomiting; specific symptoms occurring after inhaled corticosteroid treatment include hypoglycaemia with reduced state of consciousness and/or convulsions. Adrenal crisis can potentially be determined by traumas, surgery, infections and sudden reduction of posology. Patients receiving high doses should be closely assessed and their dose gradually reduced. Monitoring of adrenal reserve may also be necessary.

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 is a basic treatment of the asthmatic disease: it should be regularly taken at the prescribed doses and for as long as the physician deems it necessary.

For sportsmen:
- **use of this drug without therapeutic necessity constitutes doping and can in any case cause positive anti-doping test results;**
- **use of medicinal products containing ethyl alcohol can cause positive anti-doping test results in relation to the blood alcohol concentration limits indicated by some sports federations.**

This medicinal product is not contraindicated in people suffering from celiac disease.

Pregnancy and lactation. . In pregnant women the product should be administered in case of real need and under direct medical control. There are insufficient data on the safety of using beclomethasone dipropionate or HFA 134a propellant during pregnancy in humans. Product administration during pregnancy and lactation should be taken into consideration only if the envisaged benefit for the mother outweighs the potential risks for the foetus. It is reasonable to assume that, at the used inhaled doses, there are no important levels of

beclometasone in the mother milk. Children born from mothers who received considerable doses of inhaled corticosteroids during pregnancy should be carefully monitored in order to detect 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.

DOSE, METHOD AND FREQUENCY OF ADMINISTRATION

Adults: generally 2 inhalations twice a day. If it is thought more appropriate, the dosage can be divided into 1 inhalation 4 times a day. When necessary, the frequency can be increased to 2 inhalations 3-4 times a day. Therapy with CLENIL should not be stopped abruptly. **Children**: CLENIL 250 mcg is not suitable for paediatric use.

Instructions for use

The successful result of treatment depends on correct use of the inhaler. Test of inhaler operation: before using the inhaler for the first time or if it has not been used for three days or more, remove the mouthpiece protecting cap by gently pressing it on its sides and press once in the air to release an actuation, so as to verify the correct working of the inhaler.
For use, carefully follow the following instructions:

1) Hold the actuator between your thumb and index finger, with the mouthpiece downwards, as shown in the illustration;
2) remove the protecting cap;
3) place the mouthpiece firmly between your lips and breathe out completely;
4) take a long deep breath with your mouth only and, at the same time press once only with your index finger.

After breathing in, hold your breath as long as possible. When you have finished inhaling, close the mouthpiece again with the protecting cap. The mouthpiece should always be kept clean. Cleaning should be done with lukewarm water, after having extracted the pressurised canister.

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 promptly 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 for prolonged periods may cause adrenal suppression, growth retardation in children and adolescents, reduced bone mineral density, cataract and glaucoma. As with other inhalation therapy, paradoxical bronchospasm may occur.

The observance of the instructions contained in this 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 AND STORAGE

See the expiry date on the packaging; this date is for the unopened and correctly stored product.

ATTENTION: do not use the medicinal product beyond the expiry date indicated on the package.

PRECAUTIONS FOR STORAGE

The pressurised container should not be pierced and should be protected from heat sources, even when apparently empty. It must neither be frozen nor exposed to direct sunlight. Store below 30°C.

Keep out of the reach and sight of children

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