**CLENIL® Chiesi**
*Beclometasone + salbutamol*

**Composition**
Each pressurised canister contains:
Active ingredients: beclometasone dipropionate 0.010 g, salbutamol 0.020 g.

Excipients: sorbitan trioleate, soya lecithin, trichlorofluoromethane, dichlorodifluoromethane.

Each actuation delivers 50 mcg of beclometasone dipropionate and 100 mcg of salbutamol.

**Packaging**
Pressurised suspension for inhalation. Pressurised container sufficient for 200 inhalations.

**Pharmacotherapeutical classification**
Beta₂-selective adrenergic bronchodilator and antiasthmatic glucocorticoid for aerosol therapy.

**Therapeutic indications**
Treatment of bronchial asthma, chronic obstructive bronchial disease with asthmatic component.

**Contraindications**
Beclometasone dipropionate is contraindicated in active or quiescent local viral and tubercular infections. Subjects with individual hypersensitivity to the components (beclometasone dipropionate and salbutamol). Generally contraindicated during pregnancy and lactation (see Special warnings).

**Precautions for use**
Treatment in patients already undergoing systemic corticotherapy needs particular precautions and a strict medical control. Only after a prolonged overdosage a certain degree of corticoadrenal atrophy might occur. Sympathomimetic agents must be used very cautiously in patients who might be particularly sensitive to their effects.

In patients with coronary diseases, arrhythmiae, arterial hypertension and in patients with glaucoma, hyperthyroidism, pheochromocytoma, diabetes and prostatic hypertrophy, the product should be only used in case of absolute need.

It is important that the dose of inhaled corticosteroids is the minimum effective one to control asthma, and is regularly checked. In fact, possible systemic effects, such as adrenal suppression, even acute, delayed growth in children and teen-agers, reduction of mineral bone density, cataract and glaucoma may occur after treatment with inhaled corticosteroids at high doses and for prolonged periods. Very rare cases of adrenal crisis in teen-agers exposed to doses higher than those recommended (about 1000 mcg/day) for prolonged periods (several months or years). Symptoms of adrenal insufficiency are not specific at the beginning, and include anorexy, abdominal pain, weight loss, fatigue, headache, nausea, vomiting; specific symptoms in case of treatment with inhaled corticosteroids include hypoglycemia with reduction of consciousness state and/or convulsions. Situations possibly determining an adrenal crisis are: trauma, surgery, infections and rapid reduction of dosage. Patients receiving high doses should be strictly evaluated and the dosage gradually reduced. Monitoring of adrenal function may be necessary as well.

Its use is not recommended during the first three months of pregnancy, while in the further period a medical assessment according to the risk/benefit ratio is required to establish if the product administration is suitable.

The product should not be administered during lactation.
Its continuous use for more than 10 days is not advisable.

Always refer to the Manufacturer's Prescribing Information before you prescribe.
**Drug interactions**
Concomitant administration of the product with beta-blockers (e.g. propanol) is not recommended.

**Special warnings**
To be used only in the starting period and not for long-term treatments (the continuous use for more than 10 days is not recommended).
The use of medicinal products for topical use, especially if prolonged, might give rise to sensitization phenomena and, exceptionally, to classic systemic side effects typical of the drug. In any case, treatment must be discontinued and a suitable therapy instituted.

**Pregnancy and lactation**
The use of the product during the first three months of pregnancy is not recommended, in the following period the possibility to administer the product will be carefully considered by the physician on the basis of the risk/benefit evaluation.
The use of the product during lactation is not recommended

**Dosage and method of administration**
Adults: 2 dose-puffs up to 4-6 times a day.
Children: 1-2 puffs 2 to 4 times daily, according to the patient’s response.
The effect of a CLENIL COMPOSITUM pressurised suspension lasts for 4 hours at least.
Perform a maximum of two inhalations at a time and do not repeat the treatment before a 4-hours interval.

**Undesirable effects**
Just a few patients complained about hoarseness.
Some local mycotic infections appeared in the mouth or throat of a few patients, rapidly regressing after suitable local therapy with alkalizers or antimycotics, without discontinuing the treatment.
In some patients taking high doses of the product some transient side effects may arise (modest heart rate increase, slight muscular tremors) that disappear after the first days of treatment, reducing the dose if necessary.

Systemic side effects are extremely improbable, due to the low doses used; nevertheless, their onset might be favoured by long-term treatments.
A special caution should be paid in the prolonged use of the spray, keeping the patient under strict control in order to timely detect possible systemic side effects (osteoporosis, peptic ulcer, signs of secondary renal failure).

Adrenal suppression, delayed growth in children and teen-agers, reduction of mineral bone density, cataract and glaucoma may occur after treatment with inhaled corticosteroids at high doses used for prolonged periods.
As for other inhalation drugs, paroxysmal bronchospasm might arise.
Compliance with the instructions reported in this leaflet will reduce the risk of unwanted effects.
Promptly inform your doctor or chemist about any undesired effect not described in the present package insert.

**Expiry date and storage**
See the expiry date reported on the package; this date is to be considered for the unopened and correctly stored product.
*Attention: Do not use the product beyond the expiry date indicated on the package.*
Precautions for storage
The pressurised canister must not be pierced, placed near heating sources, even when empty, neither be frozen nor be exposed to direct sunlight. Do not store above 30°C.
Keep out of the reach of children

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