

# CLENIL® COMPOSITUM SPRAY (Salbutamol - Beclomethasone Dipropionate)

## Metered inhaler - A corticosteroid-bronchodilator combination for inhalation therapy of bronchial asthma.

CLENIL COMPOSITUM® SPRAY is a combination of a bronchodilator, salbutamol, with an active corticosteroid for inhalation, beclomethasone dipropionate.

Salbutamol is characterized by a rapid and persistent bronchial antispastic action which produces a prompt improvement of the respiratory function.

Salbutamol acts electively at the level of the bronchial musculature, without giving undesirable cardiocirculatory effects.

On the other hand, beclomethasone dipropionate controls bronchial hyperactivity, reducing oedema and hypersecretion and inhibiting progressively the onset of bronchospasm. The activity of beclomethasone dipropionate is limited to the bronchial tree without causing general effects and therefore without inhibiting adrenal function.

In order to reach full therapeutic success, it is important for the patient to accurately follow the instructions and to correctly use the inhaler.

### INDICATIONS

Bronchial asthma, asthmatic bronchitis, chronic bronchitis and emphysema with a bronchospastic component.

### DOSAGE

Adults: two puffs four to six times a day.

Children under 12 years of age: one-two puffs two to four times a day, according to therapeutic effect.

The effect of the inhalation of CLENIL COMPOSITUM® SPRAY persists for at least four hours. No more than two puffs at a time should be employed and the treatment should not be repeated before four hours.

### SIDE EFFECTS

No serious side effect has been revealed due to the use of CLENIL COMPOSITUM® SPRAY at recommended doses: only some patients have complained of hoarseness. In some patients local fungal infections have appeared in the mouth and throat; they rapidly disappear with appropriate local therapy of antimycotics without interruption of treatment.

Transitory side effects can appear at high dosages in some patients (moderate increase of cardiac frequency, light muscular tremors) but disappear after the first days of treatment, or on reduction of dosage if necessary.

Systemic side effects are extremely improbable due to the low dosage employed; their appearance, however, could be attributed to treatments of long duration.

### WARNINGS AND PRECAUTIONS

The use of topical products specially for a long time might cause phenomena of sensitization and, unusually, systemic side effects. In this case treatment must be discontinued and suitable therapy instituted.

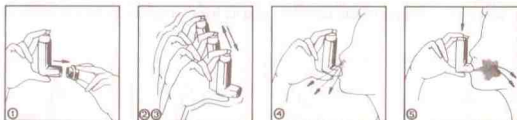
The preparation is to be used with caution in patients with ischemic cardiopathy, cardiac failure, hyperthyroidism, serious hypertension and in patients that have previously received large doses of other sympathomimetic drugs.

One should not administer this preparation together with beta-blockers (i.e. propranolol). In pregnancy, the product is to be administered in cases of real necessity and under the direct control of the physician.

### CONTRAINDICATIONS

Viral and tubercular infections, individual hypersensitivity to the components.

### INSTRUCTIONS FOR USE



1) Remove the cap from the mouthpiece

2) Hold the inhaler as illustrated.

3) Shake the inhaler.

4) Place the mouthpiece well into the mouth, close the lips firmly and make a complete expiration.

5) Start a long and deep inspiration with the mouth, and then press the metal canister downwards only once with the index finger.

After inspiration, hold breath as long as you can. Wait a few seconds before making another inhalation. Replace the cap.

The mouthpiece should be kept clean: remove the canister, rinse the mouthpiece in warm water, dry, and replace the canister.

### PACKAGING

CLENIL COMPOSITUM® SPRAY is available as a metered inhaler sufficient for 200 inhalations.



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