Cicloson™ Nasal Spray

Presentation

CiclosonTM Nasal Spray: After initial priming, each actuation delivers Ciclesonide (Micronized) 50 micrograms.

Description

Cicloson nasal spray is a corticosteroid with anti-inflammatory activity. It is an aqueous suspension of ciclesonide for topical administration to the nasal mucosa by means of a metering and atomizing spray pump. It is necessary to prime the pump before first use or after a period of non-use (4 days or more).

Indications

Cicloson nasal spray is indicated for the treatment of the symptoms of seasonal allergic rhinitis in patients aged 6 years and older and perennial allergic rhinitis in patients aged 12 years and older.

Dosage and Administration

1 spray (50 micrograms/spray) in each nostril once a day. The maximum total daily dosage should not exceed 2 sprays in each nostril (200 micrograms/day).

Priming information- Gently shake the bottle and prime Cicloson nasal spray by actuating eight times before using for the first time or when not used for 4 consecutive days.

Side effects

Ciclesonide nasal spray is absorbed less into rest of the body; therefore fewer side effects are seen. However, few side-effects like headache, dizziness, nosebleed, stuffy nose, earache may

Contraindications

Ciclesonide nasal spray is contraindicated in patients with a hypersensitivity to any of its ingredients.

Precautions

Ciclesonide nasal spray should be used with caution in patients with active or quiescent tuberculosis infection of the respiratory tract or in patients with untreated fungal, bacterial or systemic viral infections or ocular herpes simplex. Rare instances of nasal septal perforation, cataract, and glaucoma have been reported following intranasal application. Development of localized infections of the nose and pharynx with Candida albicans has rarely occurred. Although systemic effects have been minimal with recommended doses of Ciclesonide nasal spray, potential risk increases with larger doses. Therefore, larger than recommended doses of Ciclesonide nasal spray should be avoided.

Use in pregnancy and lactation

Pregnancy: Pregnancy category C. Ciclesonide nasal spray should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.

Lactation: It is not known if Ciclesonide is excreted in human milk. Because other corticosteroids are excreted in human milk, caution should be used when administered to nursing women.

Storage

- Store at a temperature not exceeding 30°C.
- Do not refrigerate.
- Protect from light and moisture.
- Keep away from eyes.
- Keep out of the reach of children.
- The bottle should be discarded after 120 actuations or 4 months after opening the pouch.

How to use the Nasal Spray

1. Tear the foil pouch at the indicated point.



2. Shake the bottle gently and remove the



3. Hold the spray with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle. If using for the first time or if you have not used it for 4 days or more, press the nasal applicator several times until a fine mist comes out from the container.



4. Gently blow the nose to clear the nostrils.



5. Close one nostril and carefully insert the nasal applicator into the open nostril. Tilt your head forward slightly and keep the spray upright. Breathe in through your nose and while breathing in, press the white collar of nasal applicator firmly down once to release a spray.



6. Breathe out through your mouth.



7. Repeat the above steps in the same/other nostril for consecutive doses.



Cleaning
The nasal spray should be cleaned at least once a week. The procedures are as follows -

- Remove the dust cover.
- Gently pull off the nasal applicator.
- Wash the applicator and dust cover in warm water.
- Shake off the excess water and leave to dry in a normal place.
- . Avoid to apply additional heat.
- Gently push the applicator back on the top of the bottle and re-fix the dust cover.

CiclosonTM Nasal Spray: Each bottle provides 120 metered sprays of Ciclesonide. Each actuation delivers Ciclesonide (Micronized) 50 micrograms

Manufactured by

