



Attention, read carefully

Allergodil® Nasal Spray

Active ingredient: Azelastine hydrochloride

Composition

Each spray puff (equivalent to 0.14 ml solution) contain 0.14 mg Azelastine hydrochloride

Other ingredients:

Sodium edetate, Methylhydroxypropyl cellulose, Dehydrated citric acid, Sodium phosphate, Sodium chloride, purified water.

Indications

For symptomatic treatment of seasonal allergic rhinitis (hay fever) or nonseasonal (perennial) allergic rhinitis.

Contraindications

Allergodil must not be used in patients with known hypersensitivity to azelastine hydrochloride, EDTA, nor in children under 6 years of age.

Usage in pregnancy and lactation

Although doses far in excess of the therapeutic range tested in laboratory animals failed to generate any evidence of teratogenic effect of the drug, current medical concepts discourage use of allergodil in the first trimester of pregnancy.

Allergodil should not be used by nursing mothers, because there is insufficient evidence of the safety of the drug during lactation.

Side-effects

In rare cases irritation of the inflamed nasal mucosa can occur on spraying, e.g. stinging, itching and sneezing. In isolated cases patient can experience nosebleeding. Improper administration (with head reclined back; see Dosage instruction and mode of use) may produce a bitter taste which may lead occasionally to nausea.

Interactions with other drugs

None known.

Dosage instruction, how to use and duration of therapy

Unless otherwise prescribed, spray once into each nostril twice daily (equivalent to a daily dose of 0.56mg Azelastine hydrochloride). Spray with head held upright (see how to use Allergodil)

Allergodil may be used until symptoms clear up, but treatment should not be continued for more than 6 consecutive months.

Stability note

Store below 25°C / Do not refrigerate

Do not use after the expiration date shown on the package.

Do not use longer 6 months after bottle was first opened.

Store drugs out of children's reach!

Presentation: Bottle containing 10 ml solution.

Marketing Authorization Holder

MEDA Pharma GmbH & Co. KG
Benzstrasse 1
61352 Bad Homburg, Germany

Manufacturer

MEDA Manufacturing GmbH
Neurather Ring 1
51063 Cologne, Germany

THIS IS A MEDICAMENT

- A medicament is a product which effects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, it benefits and risks.
- Do not by yourself interrupt the period treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of children's reach

How to use Allergodil® Nasal Spray:

- 1- Remove the head cover
- 2- Before the first use, click the pump several times till it become regular spray
- 3- spraying in every nose hole once and put your head in mid position.
- 4- Wipe and return the head cover

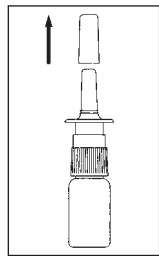


Diagram 1

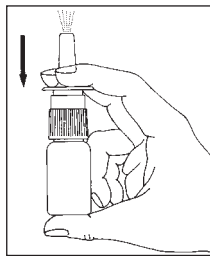


Diagram 2

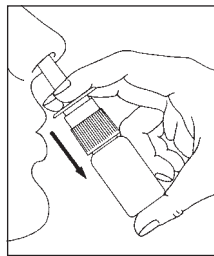


Diagram 3

Current at January 2011

