

PRESCRIBING INFORMATION
AZELAIR 0.15% NASAL SPRAY

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Indication: Symptomatic treatment of allergic rhinitis in adults, adolescents and children 6 years and older.

Presentation: Nasal pump spray containing 1.5 mg/ml azelastine hydrochloride solution. The delivered dose per actuation (0.14 ml) contains 0.21 mg azelastine hydrochloride equivalent to 0.19 mg azelastine.

Dosage and administration: *Adults and adolescents 12 years and older:* 2 sprays in each nostril once a day. In some cases, 2 sprays in each nostril twice a day may be required. The maximum daily dose is 2 sprays in each nostril twice daily. *Children 6 to 11 years:* 1 spray in each nostril twice daily. Use longer than 4 weeks is not recommended in children 6-11 years due to lack of clinical data.

Contraindications: Hypersensitivity to the active substance azelastine hydrochloride or to any of the excipients listed in section 6.1 of the SmPC.

Warning and precautions: Nothing relevant

Interaction with other medicinal products: No specific interaction studies with azelastine nasal spray have been performed. Interaction studies at high oral doses have been performed. However, they bear no relevance to Azelair as systemic levels after administration reach no more than 1/5 of the levels that were well tolerated after oral administration.

Pregnancy, lactation and fertility: There are no or limited amount of data from the use of azelastine in pregnant women. At high oral doses reproductive toxicity has been seen in animals (see section 5.3 of SmPC). Therefore, caution should be exercised when using Azelair during pregnancy. It is unknown whether azelastine/metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when azelastine is administered to a nursing woman. Effects on fertility were seen in animal studies at oral doses greater than 3.0 mg/kg/day.

Effects on ability to drive and use machines: Azelair has minor influence on the ability to drive and use machines. Rarely, the patient may experience fatigue, weariness, exhaustion, dizziness or weakness due to the disease itself, or when using Azelair. In these cases, the ability to drive and use machines may be impaired. Special attention should be paid to the fact that alcohol may enhance these effects.

Undesirable effects: Common ($\geq 1/100$ to $< 1/10$): dysgeusia (unpleasant taste). A substance-specific unpleasant taste may be experienced after administration (often due to incorrect method of application, namely tilting the head too far backwards during administration) which, in rare cases, may lead to nausea. Uncommon ($\geq 1/1,000$ to $< 1/100$): nasal discomfort (stinging, itching), sneezing, epistaxis. Please refer to SmPC for details of rare and very rare adverse events.

Legal Category: POM **Marketing Authorisation Number:** PL 46302/0085 **MAH:** Mylan Products Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK **NHS Price:** £9.90 for 20 ml bottle

Date of preparation: 04/2023
AZR-2023-0016

The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: <http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm> and from Mylan Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card Scheme website: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: pv.uk@viatris.com