Approved: 07.01.2022
Revised:

Statens legemiddelverk

OTC use in Norway for azelastine and fluticasone, ATC-code: R01AC03

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing azelastine and fluticasone. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing azelastine and fluticasone. In addition, an overview of the approvable strength(s), pharmaceutical form(s) and pack size(s) exempt from medical prescription in Norway is included.

- The proposed OTC indication and posology in the OTC package leaflet and labelling must be covered by the information approved in the corresponding SmPC.

Preparations for nasal use, up to 137 mcg/dose azelastine and 50 mcg/dose fluticasone

1. Package leaflet

1.1 Indication

Til voksne over 18 år: korttidsbehandling av plagsomme nesesymptomer ved allergi, for eksempel pollenallergi, når tidligere behandling med antihistamin eller kortikosteroid alene ikke har vært tilstrekkelig.

1.2 Posology

Change the quantity from the given strength to the number of entities to be taken (e.g. 1–2 tablets, 1 suppository, 20 ml…).

Voksne over 18 år: bruk 1 spray [137 mcg/50 mcg] i hvert nesebor 2 ganger daglig.

Kontakt lege etter 7 dager behandling hvis plagene blir verre eller ikke blir bedre.

<Product name> bør ikke brukes sammenhengende i mer enn 3 måneder. Kontakt lege dersom du har symptomer på allergi som må behandles i mer enn 3 måneder.

2. Labelling

2.1 Indication

State the indication as in the PIL. If the full indication is stated on the back panel of the package, the following abbreviation can be used on the front panel:

Mot neseplager ved allergi, når legemidler med kun ett virkestoff ikke er tilstrekkelig.

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Not applicable.

3. Content of the pack

The table below presents the highest level of the terms for approvable pharmaceutical forms, if possible. For example: the term "tablets" includes all types of tablet formulations as for example film coated tablets or chewable tablets. For active substances where some pharmaceutical forms are exempt from approval due to safety concern, this is stated explicitly below the table.

Pharmaceutical form	**Maximum strength**	**Maximum pack size**
Nasal drops or spray	137 mcg/dose 50 mcg/dose	120 doses