

OTC use in Norway for desloratadine, ATC-code: RO6AX27

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing desloratadine. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing this active substance. In addition, an overview of the approved 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.

Approved pharmaceutical form(s) and strength(s)

Preparations for oral use, up to 5 mg per unit

1. Package leaflet

This should appear in the package leaflet:

1.1 Indication

Til voksne og barn fra 6 år: Korttidsbehandling av

- øye- og neseplager ved allergi, for eksempel pollenallergi
- symptomer ved elveblest (urtikaria), som kjennetegnes av kløe og utslett med vabler

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 etc.).

Voksne og barn fra 12 år: 5 mg 1 gang daglig.

Barn 6–11 år: 2,5 mg 1 gang daglig.

Oppsøk legehjelp umiddelbart hvis du får pustevansker eller hevelse i ansiktet, i lepper, tunge eller hals.

Kontakt lege hvis plagene blir verre eller ikke blir bedre etter 3 dager.

Dersom dine øye- og neseplager vedvarer i mer enn 3 måneder må du snakke med lege. Du kan ha behov for en annen behandling.

Dersom du har elveblest som er tilbakevendende eller varer i over 2 uker må du snakke med lege. Du kan ha behov for en annen behandling.

2. Labelling

This should appear on the labelling:

2.1 Indication

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

Øye- og neseplager ved allergi og elveblest

2.2 Posology

State the dosage as in the PL.

2.3 Other information

Oppsøk legehjelp umiddelbart hvis du får pustevansker eller hevelse i ansiktet, i lepper, tunge eller hals.

Kontakt lege hvis plagene blir verre eller ikke blir bedre etter 3 dager.

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
Tablets, capsules, effervescent tablets, orodispersible tablets oral lyophilisate, granules and powder in sachets	5 mg	30

Approved date

25.02.2026

Revision history:

25.02.2026:

- Updated OTC-indication with 6 years age limit and included urticaria. Added warning to seek medical care immediately in case of symptoms of breathing difficulties or swelling in the face. Added maximum length of treatment without seeking medical advice.
- Added orodispersible tablets under approved pharmaceutical forms

20.04.2015: First version approved.