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Statens legemiddelverk

OTC use in Norway for loratadine, ATC-code: R06AX13

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing loratadine. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing loratadine. 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 oral use, up to 10 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: korttidsbehandling av øye- og neseplager ved allergi, for eksempel pollenallergi.

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 og barn over 12 år: 10 mg daglig.

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

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:

Øye- og neseplager ved allergi

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	Strength	Maximum pack size
Tablet, effervescent tablets, capsules, oral lyophilisate, granules, powder or solution in sachets	10 mg	30