

OTC use in Norway for triamcinolone, ATC-code: R01AD11

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing triamcinolone. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing triamcinolone. 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 55 mcg/dose

1. Package leaflet

1.1 Indication

Til voksne over 18 år: korttidsbehandling av 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 over 18 år: bruk 110 mikrogram i hvert nesebor 1 gang daglig. Når plagene er under kontroll, kan dosen reduseres til 55 mikrogram i hvert nesebor 1 gang daglig.

Kontakt lege etter to ukers behandling hvis plagene blir verre eller ikke blir bedre. Du får best effekt av behandlingen dersom du starter før du får allergiplager. <X> lindrer også hvis plagene allerede har startet, men det kan ta 3–4 dager før du oppnår ønsket effekt. Det er viktig å ta nesepøylen regelmessig gjennom hele pollensesongen uavhengig om du har plager eller ikke.

<X> skal ikke brukes sammenhengende i mer enn 3 måneder. Ønsker du å bruke <X> lengre, avtal dette med legen.

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:

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	Maximum strength	Maximum pack size
Nasal spray and drops	55 mcg/dose	30 doses