

OTC use in Norway for cromoglycate, ATC-code: R01AC01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing cromoglycate. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing cromoglycate. 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 5.2 mg/dose

1. Package leaflet

1.1 Indication

Til voksne og barn: korttidsbehandling av neseplager ved allergi, for eksempel pollenallergi.

1.2 Posology

Voksne og barn: 5,2 mg i hvert nesebor 2–4 ganger daglig.

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 noen uker før du oppnår lindring. Ved pollenallergi er viktig at du tar nesepøyen regelmessig gjennom hele pollensesongen uavhengig om du har plager eller ikke.

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.

2.2 Posology

State the dosage as in the PIL. However, the abbreviation below can be used:

Voksne og barn: 1 spray i hvert nesebor 2–4 ganger daglig.

2.3 Other information

Not applicable.

3. Content of the pack

Pharmaceutical form	Strength	Maximum pack size
Nasal preparations	5.2 mg/dose	15 ml