

OTC use in Norway for ipratropium and xylometazoline, ATC-code: R01AB06

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing ipratropium and xylometazoline. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing ipratropium and xylometazoline. 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, ipratropium up to 0.6 mg/ml and xylometazoline up to 0.5 mg/ml

1. Package leaflet

1.1 Indication

Til voksne over 18 år: korttidsbehandling av tett og rennende nese ved forkjølelse.

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: 84 mcg ipratropium/70 mcg xylometazoline i hvert nesebor ved behov, inntil 3 ganger daglig. Det bør gå minst 6 timer mellom hver dose.

Prøv først å behandle tett nese med saltvann (spray eller dråper) før du starter behandling med <X>.

Ikke bruk <X> sammenhengende i mer enn 7 dager. Langvarig bruk av nesenspray som inneholder xylometazoline kan føre til at du forblir tett i nesen.

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 tett og rennende nese

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 or drops	Ipratropium 0.6 mg/ml and xylometazoline 0.5 mg/ml	10 ml