



OTC USE IN NORWAY FOR IPRATROPIUMBROMIDE, XYLOMETAZOLINHYDROCHLORIDE, ATC-CODE: R01AB06

- To gain OTC prescription status for a medicinal product an application in accordance with “A guideline on changing the classification for the supply of a medicinal product for human use” should be submitted.
- This substance report presents the preferred wording for PIL and packaging material for OTC prescription status for Ipratropiumbromide, Xylometazolinhydrochloride in Norway.
- To make use of this report, the application for OTC prescription status must be:
 - within the scope of what is already approved as OTC use for Ipratropiumbromide, Xylometazolinhydrochloride in Norway
 - covered in the approved and/or sought SPC for the product in question

Nasal spray, solution

0.6 mg/ml ipratropiumbromide / 0.5 mg/ml xylometazolinhydrochloride

PACKAGE LEAFLET INFORMATION (OTC)

INDICATION

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

DOSAGE

Voksne over 18 år: 1 spray 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 {trade name}. Ikke bruk {trade name} sammenhengende i mer enn 7 dager. Langvarig bruk av nesespray som inneholder xylometazolin kan føre til at du forblir tett i nesen.

LABELLING INFORMATION

INDICATION

The indication should be written as in the PIL. If the full indication is written on the back panel of the package the following short form can be used on the front panel:

Tett og rennende nese

DOSAGE

The dosage should be written as in the PIL.



OTHER INFORMATION

Not applicable.

PACK SIZE

Pharmaceutical form	Strength	Maximum pack size
Nasal spray, solution	0.6 mg/ml ipratropiumbromide / 0.5 mg/ml xylometazolinhydrochloride	10 ml

Approved (date): 07.04.2014