



OTC use in Norway for carbomer, ATC-code: S01XA2

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing carbomer. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing carbomer. 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 ocular use, carbomer up to 2.5 mg/g (or 2.5 mg/ml)

1. Package leaflet

1.1 Indication

Til voksne: lindrer symptomer på tørre øyne.

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: 1 dråpe i hvert øye 3-4 ganger daglig etter behov.

Kontakt lege 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:

Lindrer symptomer på tørre øyne

2.2 Posology

State the dosage as in the PIL.

Approved: 25.07.2019

Revised:

Statens legemiddelverk

Norwegian Medicines Agency



2.3 Other information

<Not applicable.>

3. Content of the pack

Pharmaceutical form	Strength	Maximum pack size
Eye drops	Up to 2.5 mg/ml	30 ml
Eye gel	Up to 2.5 mg/g	30 g