

OTC use in Norway for meclozine, ATC-code: R06AX13

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing meclozine. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing meclozine. 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 oral use, up to 25 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 6 år: reisesykemiddel som motvirker kvalme og brekninger.

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 og barn over 12 år: Ta 25-50 mg 1–2 timer før avreise. Ta en ny dose når kvalmen kommer tilbake. Ikke ta mer enn 50 mg i løpet av 24 timer.

Barn 6–12 år: Gi 12,5 mg 1-2 timer før avreise. Du kan gi en ny dose etter det har gått 12 timer.

Kontakt lege etter 7 dager 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:

Reisesykemiddel

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Kan medføre døsighet. Du bør ikke kjøre bil eller bruke maskiner etter å ha tatt <X>.

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	Strength	Maximum pack size
Tablets, orodispersible tablets, lozenges, capsules, oral lyophilisate, granules, oral solution or powder in sachets	25 mg	10