

OTC use in Norway for pentoxyverine, ATC-code: R05DB05

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing pentoxyverine. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing this active substance. In addition, an overview of the approved 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.

Approved pharmaceutical form(s) and strength(s)

Oral solution, 2.13 mg/ml pentoxyverine citrate (equiv. 1.35 mg/ml pentoxyverine)

1. Package leaflet

This should appear in the package leaflet:

1.1 Indication

Til voksne og barn fra 6 år: Hostedempende ved tørrhoste.

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 etc.).

Liquid formulations

Age	Weight	Dosage*
Children 6–15 years	20–26 kg	10.7 mg 3–4 times daily
	27–45 kg	16.0 mg 3–4 times daily
	46–60 kg	32.0 mg 3–4 times daily
Adults and children > 15 years	> 60 kg	32.0 mg 3–4 times daily

*Refers to pentoxyverine citrate

Bruk vedlagt målebeger.

Du må kontakte lege dersom du ikke føler deg bedre etter 10 dager eller hvis du føler deg verre.

<X> skal ikke brukes sammenhengende i mer enn 2 uker.

1.3 Other information

The risks of use in elderly patients (> 65 years of age) must be properly addressed in the PL, including information regarding concomitant medications with anticholinergic effects.



2. Labelling

This should appear on the labelling:

2.1 Indication

Til voksne og barn fra 6 år: Hostedempende ved tørrhoste

2.2 Posology

State the dosage as in the PL. However, shortened if needed.

2.3 Other information

Skal ikke brukes av gravide og ammende. Skal ikke gis til barn under 6 år.

Dersom du er over 65 år og bruker andre legemidler, skal du snakke med lege før bruk.

Du må kontakte lege dersom du ikke føler deg bedre etter 10 dager eller hvis du føler deg verre.
<X> skal ikke brukes sammenhengende i mer enn 2 uker.

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.

Pharmaceutical form	Maximum strength	Maximum pack size
Oral solution	2.13 mg/ml pentoxyverine citrate (equiv. 1.35 mg/ml pentoxyverine)	200 ml

Approved date

Approved: 08.05.2024