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Statens legemiddelverk

OTC use in Norway for lactulose, ATC-code: A06A D11

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing lactulose. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing lactulose. 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, lactulose up to 670 mg/ml or 10 g per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 1 år: behandling av forstoppelse.

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…). Include only the age group(s) for which the pharmaceutical form and strength is suitable. The text below include the posology and the necessary information included for the most commonly used pharmaceutical dose forms.

For all pharmaceutical forms – dosage per 24 hours:

Alder	Startdose	Vedlikeholdsdose
Over 14 år	10–30 g	10–20 g
3–14 år	7–10 g	7–10 g
1–3 år	3–7 g	

Example:
Barn 3-14 år:
Startdose er 7-10 g i løpet av 24 timer.
Vedlikeholdsdosen er 7-10 g i løpet av 24 timer.

Du kan ta dosen som en engangsdose eller fordele den på to ganger. Bruk målebeger. Når du har fått god effekt kan startdosen kan du trappe ned til vedlikeholdsdose (se tabell). Det tar som regel 2–4 dager før du oppnår god effekt. Ved langvarig forstoppelse bør du kontakte lege.

<X> kan blandes i mat eller drikke, som for eksempel i saft, te, juice, kakao, yoghurt eller grøt.
For å få god effekt av <X> er det viktig at du drikker mye.

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 forstoppelse

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
Oral solution, oral gel	670 mg/ml	1000 ml
Oral solution or oral gel in sachet	10 g/15 ml	100