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Statens legemiddelverk

OTC use in Norway for loperamide, ATC-code: A07DA03

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing loperamide. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing loperamide. 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 0.2 mg/ml or 2 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 12 år: korttidsbehandling av akutt diaré.

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…). The text below include the posology and the necessary information included for the most commonly used pharmaceutical dose forms.

Voksne og barn over 12 år: start behandlingen med 4 mg. Deretter tar du 2 mg etter hver løs avføring. Vent 2–3 timer mellom hver gang du tar <produktnavn>. Ikke ta mer enn 16 mg i løpet av 24 timer.

Hvis du fortsatt har diaré etter 48 timer må du slutte å ta legemidlet og kontakte lege.

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:

Korttidsbehandling av akutt diaré

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Dersom du er gravid eller ammer skal du kun bruke <produktnavn> etter avtale med lege.

Ikke bruk <produktnavn> om du har høy feber (over 39 °C) eller blod i avføringen - da må du kontakte lege.

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**
Tablets, capsules, oral solution in sachet	2 mg	16
Oral solution	0.2 mg/ml	100 ml