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Statens legemiddelverk

OTC use in Norway for bisacodyl, ATC-code: A06A B02 and A06A G02

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

1. Package leaflet

1.1 Indication

Til voksne og barn over 10 år: korttidsbehandling mot forstoppelse og til bruk før røntgenundersøkelse eller operative inngrep.

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.

<u>Korttidsbehandling av forstoppelse:</u>
For peroral formulations:
Voksne og barn over 10 år: ta 5-10 mg 1 gang daglig ved sengetid.
For rectal formulation:
Voksne og barn over 10 år: 10 mg føres inn i endetarmen 1 gang daglig for umiddelbar effekt.

<Produktnavn> skal ikke brukes sammenhengende i mer enn 1 uke.

<u>Forberedelse før røntgenundersøkelse eller operative inngrep</u>:
Voksne og barn over 10 år: ta 10 mg <peroral legemiddelform> om morgenen og 10 mg <peroral legemiddelform> om kvelden ved sengetid dagen før undersøkelsen.
Om morgenen på undersøkelsesdagen føres 10 mg <rektal formulering> inn i endetarmen.

2. Labelling

2.1 Indication

State the indication as in the PIL.

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**
Tablets, granules, capsules	5 mg	30
Suppository	10 mg	10
Rectal liquid	10 mg/5 ml	10 x 5 ml
Combination package (peroral + rectal formulation)	5 mg peroral formulation + 10 mg or 10 mg/5 ml rectal formulation	4 + 1