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Statens legemiddelverk

OTC use in Norway for potassium iodide, ATC-code: V03AB21

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing potassium jodide. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing potassium iodide. 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 130 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn fra 0 år: beskyttelse mot radioaktivt jod ved atomulykker

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 < 40 år: 130 mg som enkeltdose
Barn 12–18 år: 130 mg som enkeltdose
Barn 3–12 år: 65 mg som enkeltdose
Barn 1 måned – 3 år: 32,5 mg som enkeltdose
Barn 0–1 måned: 16,25 mg som enkeltdose

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:

Beskyttelse mot radioaktivt jod ved atomulykker

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Følg alltid aktuelle råd fra myndighet.

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, granules	130 mg	100