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Statens legemiddelverk

OTC use in Norway for metronidazole ATC-code: D06BX01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing metronidazole. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing metronidazole. 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 cutaneous use, up to 7.5 mg/g or 7.5 mg/ml

1. Package leaflet

1.1 Indication

Til voksne over 18 år: behandling av milde former av hudsykdommen rosacea. Du kan først starte behandling etter at diagnosen har blitt stilt av lege.

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 over 18 år: påfør <produktnavn> morgen og kveld. Behandlingsperioden er vanligvis 3–4 måneder.

Kontakt lege hvis plagene blir verre eller ikke blir bedre.

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:

Milde former av rosacea etter at diagnosen er stilt av lege.

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**
Cream, gel, emulsion	7.5 mg/g	30 g
Solution	7.5 mg/ml	30 ml