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Statens legemiddelverk

OTC use in Norway for fluconazole ATC-code: J02AC01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing fluconazole. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing fluconazole. 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 150 mg per unit

1. Package leaflet

1.1 Indication

Kvinner i alderen 18-50 år: behandling av soppinfeksjon i skjeden. Brukes dersom behandling med krem/stikkpiller i og rundt skjeden ikke er egnet eller ikke har effekt. Du må tidligere ha fått diagnosen av lege så du kjenner igjen symptomene på soppinfeksjon.

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…).

Kvinner i alderen 18-50 år: ta 150 mg som engangsdose.

Kontakt lege innen 3 dager etter behandling hvis plagene blir verre eller ikke blir bedre.

Kontakt lege dersom soppinfeksjonen kommer tilbake mer enn 2 ganger i løpet av en 6 måneders periode etter behandling.

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:

Soppinfeksjon i skjeden.

2.2 Posology

State the dosage as in the PIL. However, the abbreviation below can be used.

Kvinner i alderen 18-50 år: ta 1 <legemiddelform> som engangsdose.

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
Capsule, tablet, granules or powder in sachet	150 mg	1