

OTC use in Norway for estradiol, ATC-code: G03CA03

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing estradiol. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing estradiol. 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 vaginal use, estradiol up to 10 microgram per unit

1. Package leaflet

1.1 Indication

Kvinner etter overgangsalderen (etter siste regelmessige menstruasjonsperiode): behandling av plager i skjeden som skyldes mangel på østrogen.

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...).

Startdose: 10 mikrogram føres inn i skjeden daglig i 2 uker.

Vedlikeholdsbehandling: 10 mikrogram føres inn i skjeden 2 ganger per uke.

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:

Lokalbehandling av plager i skjeden etter overgangsalder

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Not applicable.

3. Content of the pack

Pharmaceutical form	Maximum strength	Maximum pack size
Vaginal tablet	10 mcg	18