



OTC use in Norway for tadalafil, ATC-code: G04B E08

- This OTC (over-the-counter) substance report is based on the assessment of the OTC indication and posology for products containing tadalafil. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing this active substance. In addition, an overview of the approved 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.

Approved pharmaceutical form(s) and strength(s)

Tadalafil 10 mg tablets

1. Package leaflet

This should appear in the package leaflet:

1.1 Indication

<Invented name> er en behandling for menn fra 18 år med impotens.

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 etc.).

Ta 10 mg ved behov ca. 30 minutter før forventet seksuell aktivitet.

<Invented name> kan virke i opptil 36 timer. Ikke ta mer enn 10 mg per dag.

<Invented name> skal ikke brukes daglig. Snakk med lege hvis du føler du ofte har behov for å ta <Invented name> (dvs. minst 2 ganger per uke).

2. Labelling

This should appear on the labelling:

2.1 Indication

State the indication as in the PL. If the full indication is stated on the back panel of the package, the following can be used on the front panel:

Menn fra 18 år: behandling av impotens



2.2 Posology

Ta 10 mg ved behov ca. 30 minutter før forventet seksuell aktivitet. <Invented name> kan virke i opptil 36 timer.

Ikke ta mer enn 10 mg per dag. <Invented name> skal ikke brukes daglig.

2.3 Other information

Ikke bruk <Invented name> dersom du:

- har brystmerter (angina)
- tar nitratmedisiner mot brystmerter eller hjertesvikt
- har lavt blodtrykk
- har høyt blodtrykk som ikke er godt behandlet
- tar legemiddelet riociguat mot høyt blodtrykk i lungene
- har uregelmessig hjerterytme eller hjertebank
- har hatt alvorlig synstap eller har arvelig øyesykdom

3. Content of the pack

Approved pharmaceutical form(s), strength(s) and pack size(s) exempt from medical prescription in Norway:

Pharmaceutical form	Maximum strength	Maximum pack size
Tablet	10 mg	8

4. Additional risk minimisation measures

Conditions for dispensing the product: *Reseptfri med veiledning. Utleveres av farmasøyt.*

Material to be used as part of the mandatory guidance will be published on NOMA's webpage.

Educational material for the pharmacist is required and provided by the MAH.

Pharmacists must ensure that only pharmacists who have completed the education program may sell the product.

The product shall be placed behind the pharmacy counter.

The product can only be sold to customers who meet the required conditions and who have been provided with the counselling information.



The product may be sold through internet pharmacies in Norway. The internet pharmacy may use an online check list, however, the pharmacy must ensure an adequate interaction between customer and pharmacist before dispensing the product in order to be able to provide individual guidance and advice to each customer.

Approved date

30.06.2025

Revision history:

30.06.2025: First version approved