Norwegian Medical Products Agency

OTC use in Norway for sildenafil, ATC-code: G04B E03

- This OTC (over-the-counter) substance report is based on the assessment of the OTC indication and posology for products containing sildenafil. 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)

Preparations for oral use, sildenafil 50 mg per unit

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 50 mg ved behov omtrent 1 time før seksuell aktivitet.
Ikke ta mer enn 50 mg daglig.

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 short form can be used on the front panel:

Menn fra 18 år: behandling av impotens

2.2 Posology

State the dosage as in the PL.

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2.3 Other information

Ikke bruk <active substance or invented name> dersom du:

- har brystsmerter (angina)
- tar nitratmedisiner mot brystsmerter 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
- tar legemiddelet ritonavir mot virusinfeksjon

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
Tablets, capsules	50 mg	8
Orodispersible film	50 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 NOMAs webpage.

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

Pharmacies 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 patients who meet the check list 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

25.06.2026

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Revision history:

25.06.2026: Inclusion of orodispersible film. Minor updates to the wording for indication and posology. Updated labelling warning: inclusion of riociguat and ritonavir. All warnings are now listed under «Do not use».

22.08.2019: First version approved.