

OTC use in Norway for sildenafil, ATC-code: G04BE03

- This OTC 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 sildenafil. 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, sildenafil 50 mg per unit

1. Package leaflet

1.1 Indication

<Produktnavn> er en behandling for menn over 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...).

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

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:

Menn over 18 år: behandling ved impotens

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Ikke bruk <produktnavn> dersom du:

- tar nitratmedisiner mot bryst smerter eller hjertesvikt
- har hjertekramper/bryst smerter (angina)
- har lavt blodtrykk
- har hatt alvorlig synstap eller arvelig øyesykdom

Snakk med lege før du tar legemidlet dersom du:

- har høyt blodtrykk som ikke er godt behandlet
- har uregelmessige hjerteslag/hjertebank

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	Strength	Maximum pack size
Tablet, capsules	50 mg	8

4. Additional risk minimisation measures

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

A pharmacy check list is required and published here:

<https://legemiddelverket.no/Documents/Bivirkninger%20og%20sikkerhet/Risikominimering%20stiltak/Sjekkliste%20sildenafil%20reseptfri.pdf>

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. The product can therefore not be

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ordered or sold in the absence of a pharmacist, for example during evening hours, night and Sundays or public holidays.