

## OTC use in Norway for folic acid, ATC-code: B03BB01

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing folic acid. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing folic acid. 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 0.4 mg per unit

#### 1. Package leaflet

##### 1.1 Indication

Til voksne over 18 år: til kvinner som planlegger å bli gravide eller er gravide i graviditetens første tre måneder. Brukes også forebyggende til behandling av folsyremangel ved feilernæring eller ved økt behov.

##### 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...).*

Voksne over 18 år: 0,4 mg daglig.

Gravide: 0,4 mg daglig i de første 3 månedene av graviditeten.

#### 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:*

Ved økt folsyrebehov.

##### 2.2 Posology

*State the dosage as in the PIL.*

##### 2.3 Other information

Not applicable

### 3. Content of the pack

Pharmaceutical form	Strength	Maximum pack size
Tablet	0.4 mg	100