# otc use in Norway for valerian root, ATC-code: N05C M09

* To gain OTC prescription status for a medicinal product an application in accordance with “A guideline on changing the classification for the supply of a medicinal product for human use” should be submitted.

* This substance report presents the preferred wording for PIL and packaging material for OTC prescription status in Norway.

* To make use of this report, the application for OTC prescription status must be:
* within the scope of what is already approved as OTC use for valerian root in Norway
* covered in the approved and/or sought SPC for the product in question
* **Herbal preparations with well-established use covered by the European Union herbal monograph on Valeriana officinalis L., radix published on www.ema.europa.eu**

**Valerian root preparations with a Well-established use marketing authorisation**

**(Article 10a of** [**Directive 2001/83/EC**](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons/dir2001_83_cons_20081230_en.pdf)**) on the Norwegian market:**

**Coated tablets**

445 mg of extract (as dry extract) from *Valeriana officinalis* L., radix (valerian root).

200 mg of extract (as dry extract) from *Valeriana officinalis* L., radix (valerian root).

## Package leaflet information

### Indications according to national decisions:

Voksne og barn over 12 år: lindrer mild uro og søvnforstyrrelser.

**Labelling information**

**Indications:**

*The indication should be written as in the PIL.*

## Pack size

|  |  |  |
| --- | --- | --- |
| **Pharmaceutical form**  | **Strength** | **Maximum pack size** |
| Coated tablets | N/A | 240 tablets |

**Approved (date): 24.10.2017**