

OTC USE IN NORWAY FOR IVY LEAF (*HEDERA helix* L., FOLIUM) PREPARATIONS*, ATC-CODE: R05C A12

- 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 for *Hedera helix* L. preparations* 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 *Hedera helix* L. preparations in Norway
 - covered in the approved and/or sought SPC for the product in question

PACKAGE LEAFLET INFORMATION (OTC)

Indication

Plantebasert legemiddel
Voksne og barn over 6 år: ved slimhoste

Dosage

The quantity shall be transformed from mg to the number of entities to be taken (e.g. 1-2 tablets, 1 suppository, 20 ml...) in the PIL. Include only the age group(s) for which the pharmaceutical form and strength is suitable.

Voksne og barn over 12 år: 15-65 mg, 1-3 ganger daglig.

Barn 6 - 11 år: 11- 35 mg, 2-3 ganger daglig.

Kontakt lege innen 7 dagers behandling hvis plagene blir verre eller ikke blir bedre.

LABELLING INFORMATION

Indication

The indication should be written as in the PIL.

If the full indication is written on the back panel of the package the following short form can be used on the front panel:

Plantebasert legemiddel
Voksne og barn over 6 år: ved slimhoste

Dosage

The dosage should be written as in the PIL.

Other information

Not applicable.

PACK SIZE

Pharmaceutical form	Strength	Maximum pack size
Syrup	The information should be in line with the European Union herbal monograph on Hedera helix L., folium, EMA/HMPC/586888/2014.	100 ml

*(European Union herbal monograph on Hedera helix L., folium, EMA/HMPC/586888/2014)

Approved (date): 12.10.2016