LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nicovel Mint
(nicotine)

SE/H/1316/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Nicovel Mint

(nicotine)

Oromucosal powder in pouch, 4 mg

This is a summary of the public assessment report (PAR) for Nicovel Mint. It explains how Nicovel Mint was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Nicovel Mint.

For practical information about using Nicovel Mint, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nicovel Mint and what is it used for?

Nicovel Mint is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as oromucosal powder in pouch instead of medicated chewing-gum. The reference medicine for Nicovel Mint is Nicorette medicated chewing-gum.

Nicovel Mint is used for relief of withdrawal symptoms and craving for nicotine in relation with smoking cessation or reduction in adults.

Nicovel Mint facilitates smoking reduction in smokers who cannot or are unwilling to stop smoking completely. It is indicated for adults aged 18 years and above.

How does Nicovel Mint work?

Nicovel Mint contains the active substance nicotine. If a person suddenly stops providing nicotine in the form of tobacco to one's body, they experience different kinds of discomfort, called withdrawal symptoms. When using Nicovel Mint it prevents or reduces the discomfort, by continuing to provide a small amount of nicotine to the body during a transitional period.

How is Nicovel Mint used?

The pharmaceutical form of Nicovel Mint is oromucosal powder in pouch. The pouch should be placed under the upper lip and be kept there for approximately 30 minutes.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can be obtained without a prescription.

What benefits of Nicovel Mint have been shown in studies?

Nicovel Mint is a hybrid application of Nicorette. Bridging data between Nicovel Mint and the reference product Nicorette has been provided.

What are the possible side effects of Nicovel Mint?

For the full list of all side effects reported with Nicovel Mint, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Nicovel Mint approved?

This medicine is similar to a reference medicine containing the same active substance, but is available as oromucosal powder in pouch instead of medicated chewing-gum.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Nicovel Mint's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Nicovel Mint?

A risk management plan has been developed to ensure that Nicovel Mint is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Nicovel Mint, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Nicovel Mint

The marketing authorisation for Nicovel Mint was granted on 2014-07-03 in Sweden.

The full PAR for Nicovel Mint can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Nicovel Mint, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2018-10.