LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nicotinell Fruktmint
(nicotine)

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(nicotine)

compressed lozenge, 1 mg and 2 mg

This is a summary of the public assessment report (PAR) for Nicotinell Fruktmint. It explains how Nicotinell Fruktmint 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 Nicotinell Fruktmint.

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

What is Nicotinell Fruktmint and what is it used for?

Nicotinell Fruktmint is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as compressed lozenges instead of medicated chewing gum. The reference medicine for Nicotinell Fruktmint is Nicorette.

The company has provided additional own data to demonstrate the safety and efficacy of Nicotinell Fruktmint regarding this difference from the reference medicine.

Nicotinell Fruktmint is used to help patients stop smoking.

How does Nicotinell Fruktmint work?

The nicotine in Nicotinell Fruktmint relieves nicotine withdrawal symptoms and cravings when patients stop smoking or temporarily reduce smoking in order to facilitate smoking cessation. By relieving the withdrawal symptoms and cravings Nicotinell Fruktmint counteracts a smoking relapse in smokers who are motivated to stop smoking.

How is Nicotinell Fruktmint used?

The pharmaceutical form of Nicotinell Fruktmint is compressed lozenges which should be sucked in order to slowly release the nicotine so it can be absorbed through the lining of the mouth.

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 Nicotinell Fruktmint have been shown in studies?

Because Nicotinell Fruktmint is a hybrid application of Nicorette medicated chewing gum, clinical studies have been provided for Nicotinell Fruktmint to show efficacy for the difference of Nicotinell Fruktmint from the reference product Nicorette.

What are the possible side effects of Nicotinell Fruktmint?

For the full list of all side effects reported with Nicotinell Fruktmint see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

Why is Nicotinell Fruktmint approved?

This medicine is similar to a reference medicine containing the same active substance, but is available as compressed lozenges instead of medicated chewing gum. The company has provided additional own data to demonstrate the safety and efficacy of Nicotinell Fruktmint regarding this difference from the reference medicine.
No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Nicotinell Fruktmint'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 Nicotinell Fruktmint?

A risk management plan has been developed to ensure that Nicotinell Fruktmint 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 Nicotinell Fruktmint, 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 Nicotinell Fruktmint

The marketing authorisation for Nicotinell Fruktmint was granted on 2014-12-04 in Sweden.

The full PAR for Nicotinell Fruktmint can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Nicotinell Fruktmint, please read the package leaflet 1 mg and the package leaflet 2 mg or contact your doctor or pharmacist.

This summary was last updated in 2016-10.