

Summary Public Assessment Report

Nicorama Mint/Nicorama Frukthemint (nicotine resinate)

SE/H/2016/01-04/MR

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nicotine resinate

Medicated chewing-gum, 2 mg, 4 mg

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

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

What is Nicorama Mint/Nicorama Fruktmint and what is it used for?

Nicorama Mint/Nicorama Fruktmint is a 'generic medicine'. This means that Nicorama Mint/Nicorama Fruktmint is similar to a 'reference medicine' already authorised in the European Union (EU) called Nicorette.

Nicorama Mint/Nicorama Fruktmint can be used by people who wish to stop smoking.

How does Nicorama Mint/Nicorama Fruktmint work?

The nicotine in Nicorama Fruitmint relieves nicotine cravings and withdrawal problems when stopping smoking, thereby preventing relapse to smoking in smokers who are motivated to stop. The aim of the treatment is permanent cessation of tobacco use.

How is Nicorama Mint/Nicorama Fruktmint used?

The pharmaceutical form of Nicorama Mint/Nicorama Fruktmint is medicated chewing-gum for oral use.

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 in Sweden.

What benefits of Nicorama Mint/Nicorama Fruktmint have been shown in studies?

Because Nicorama Mint/Nicorama Fruktmint is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Nicorette.

What are the possible side effects of Nicorama Mint/Nicorama Fruktmint?

Because Nicorama Mint/Nicorama Fruktmint is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Nicorama Mint/Nicorama Fruktmint approved?

It was concluded that, in accordance with EU requirements, Nicorama Mint/Nicorama Fruktmint has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Nicorette. Therefore, the Medical Products Agency in Sweden decided that, as for Nicorette, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Nicorama Mint/Nicorama Fruktmint?

A risk management plan has been developed to ensure that Nicorama Mint/Nicorama 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 Nicorama Mint/Nicorama 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 Nicorama Mint/Nicorama Fruktmint

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

This summary was last updated in 2020-10.