

Summary Public Assessment Report

Nicorette Frukthemint (nicotine)

SE/H/904/02/DC

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(nicotine)

Oromucosal spray, solution, 1 mg/spray

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

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

What is Nicorette Fruktmint and what is it used for?

Nicorette Fruktmint is used to help you stop smoking when you want to quit. This is a type of treatment called Nicotine Replacement Therapy (NRT).

How does Nicorette Fruktmint work?

Nicorette Fruktmint relieves nicotine withdrawal symptoms including cravings, symptoms you get when stopping smoking. When you suddenly stop providing nicotine from tobacco to your body, you get hit by different kinds of unpleasant feelings called withdrawal symptoms.

By using Nicorette Fruktmint you can prevent or reduce these unpleasant feelings and cravings for smoking. This is because you continue to provide a small amount of nicotine to your body for a short period of time.

Nicorette Fruktmint does not contain the tar, carbon monoxide or other toxins in cigarette smoke.

How is Nicorette Fruktmint used?

The pharmaceutical form of Nicorette Fruktmint is Oromucosal spray 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.

What benefits of Nicorette Fruktmint have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Nicorette Fruktmint is effective in treating of tobacco dependence in adults by relief of nicotine withdrawal symptoms, including cravings, during a quit attempt. Permanent cessation of tobacco use is the eventual objective. Nicorette Fruktmint should preferably be used in conjunction with a behavioral support program

The difference between the previously approved oromucosal nicotine spray and the newly developed is restricted to the flavouring, a minor part of the formulation.

What are the possible side effects of Nicorette Fruktmint?

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

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

Why is Nicorette Fruktmint approved?

It was noted that the effect of Nicorette Fruktmint in the treatment of tobacco dependence in adults by relief of nicotine withdrawal symptoms, including cravings, during a quit attempt was significantly better than treatment with placebo. The difference between the previously approved oromucosal nicotine spray and the newly developed is restricted to the flavouring, a minor part of the formulation.

Therefore, the Medical Products Agency in Sweden decided that Nicorette 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 Nicorette Fruktmint?

A risk management plan has been developed to ensure that Nicorette 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 Nicorette 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 Nicorette Fruktmint

The marketing authorisation for Nicorette Fruktmint was granted on 2017-11-03 in Sweden.

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

This summary was last updated in 2017-11.