

Summary Public Assessment Report

Nicorette Pepparmint (nicotine resinate)

SE/H/1617/01-02/E/01

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nicotine resinate

Compressed lozenge, 2 mg, 4 mg

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

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

What is Nicorette Pepparmint and what is it used for?

Nicorette Pepparmint is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called NiQuitin.

This medicine is used to relieve withdrawal symptoms and reduce the cravings for nicotine that you get when you try to stop smoking or when you are cutting down the number of cigarettes you smoke while trying to stop smoking. The treatment is for adult smokers 18 years and above.

Nicorette Pepparmint 2 mg Lozenges are suitable for smokers who have a low nicotine dependency e.g. who either have their first cigarette of the day more than 30 minutes after waking up or who smoke 20 cigarettes or less per day.

Nicorette Pepparmint 4 mg lozenges are suitable for smokers with high nicotine dependency e.g. those smoking their first cigarette of the day within 30 minutes after waking up or those who smoke more than 20 cigarettes per day.

How does Nicorette Pepparmint work?

Nicorette Pepparmint relieves the nicotine withdrawal symptoms, including cravings, you get when you stop smoking. When your body suddenly stops getting nicotine from tobacco, you get hit by different kinds of unpleasant feelings called withdrawal symptoms, such as irritability, feeling angry or low, anxiety, restlessness, poor concentration, increased appetite or weight gain, urges to smoke (craving), night time awakening or sleep disturbance. The nicotine in Nicorette Pepparmint can help prevent or reduce these unpleasant feelings and cravings for smoking.

How is Nicorette Pepparmint used?

The pharmaceutical form of Nicorette Pepparmint is compressed lozenges 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 Nicorette Pepparmint have been shown in studies?

Because Nicorette Pepparmint is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, NiQuitin. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Nicorette Pepparmint?

Because Nicorette Pepparmint 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 side effects, see section 4 of the package leaflet.

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

Why is Nicorette Pepparmint approved?

It was concluded that, in accordance with EU requirements, Nicorette Pepparmint has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for NiQuitin, 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 Nicorette Pepparmint?

A risk management plan has been developed to ensure that Nicorette Pepparmint 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 Pepparmint, 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 Pepparmint

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

This summary was last updated in 2022-09.