

# **Summary Public Assessment Report**

## **Zonnic Pepparmint (nicotine)**

**SE/H/776/03/E01**

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Zonnic Pepparmint  
(nicotine)

Oromucosal spray; 1 mg/spraying

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

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

### **What is Zonnic Pepparmint and what is it used for?**

Zonnic Pepparmint is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as another pharmaceutical form.

The company has provided additional own data to demonstrate the safety and efficacy of Zonnic Pepparmint regarding this difference from the reference medicine. The reference medicine for Zonnic Pepparmint is Nicorette.

The nicotine in Zonnic Pepparmint relieves craving for nicotine and withdrawal symptoms when you stop smoking and counteracts thereby relapse into smoking in smokers who are motivated to stop or to facilitate reduction of smoking for smokers who cannot or are unwilling to stop smoking completely.

### **How does Zonnic Pepparmint work?**

When you suddenly stop providing nicotine in the form of tobacco to your body, you get hit by different kinds of discomfort, called withdrawal symptoms. By means of Zonnic Pepparmint you can prevent or at least reduce this discomfort, by continuing to provide a small amount of nicotine to your body during a short period of time.

Advice and support normally improve the success rate.

### **How is Zonnic Pepparmint used?**

The pharmaceutical form of Zonnic Pepparmint 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 Zonnic Pepparmint have been shown in studies?**

Because Zonnic Pepparmint is a hybrid application of Nicorette, clinical studies have been provided for Zonnic Pepparmint to show efficacy for the difference of Zonnic Pepparmint from the reference product Nicorette.

### **What are the possible side effects of Zonnic Pepparmint?**

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

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

### **Why is Zonnic Pepparmint approved?**

This medicine is similar to a reference medicine containing the same active substance, but is available as another pharmaceutical form. The company has provided additional own data to demonstrate the safety and efficacy of Zonnic Pepparmint 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 Zonnic Pepparmint'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 Zonnic Pepparmint?**

A risk management plan has been developed to ensure that Zonnic 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 Zonnic 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 Zonnic Pepparmint**

The marketing authorisation for Zonnic Pepparmint was granted on 2008-08-01 in Sweden.

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

This summary was last updated in 2016-06.