

**Leaflet: Information for the user**  
**Nicorette 2 and 4 mg medicated chewing gum**  
**Nicorette Peppermint 2 and 4 mg medicated chewing gum**  
**Nicorette Fruitmint 2 and 4 mg medicated chewing gum**

nicotine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist, or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any side effects not listed in this leaflet. See section 4.
- You must talk to a healthcare professional if you are unable to taper off, stop smoking or are unable to stop using Nicorette. See section 3.

**What is in this leaflet:**

1. What Nicorette is and what it is used for
2. What you need to know before you take Nicorette
3. How to use Nicorette
4. Possible side effects
5. How to store Nicorette
6. Contents of the pack and other information

**1. What Nicorette is and what it is used for**

Nicorette belongs to a group of medicines that are used to help you quit smoking.

The nicotine in Nicorette relieves nicotine cravings and withdrawal symptoms when you quit smoking, thereby preventing relapse in smokers who are motivated to quit or to facilitate smoking reduction (tapering before quitting) in smokers who are unable or unwilling to quit.

The treatment is intended for smokers over the age of 18.

When the body suddenly no longer receives nicotine from tobacco, various discomforts known as withdrawal symptoms occur. Using Nicorette chewing gum can prevent or relieve such discomfort and cravings to smoke by continuing to supply your body with a small amount of nicotine for a transitional period. When you chew Nicorette, nicotine is released slowly and absorbed into the oral cavity. Unlike cigarettes, Nicorette does not contain harmful tar or carbon monoxide.

Nicorette chewing gum should ideally be used in conjunction with a smoking cessation program. Advice and support normally increase the chance of success with your smoking cessation.

**2. What you need to know before you take Nicorette**

**Do not take Nicorette**

- if you are **allergic** to nicotine or any of the other ingredients of this medicine (listed in section 6)
- if you are under 12 years of age
- if you have never smoked

### Warnings and precautions

Talk to your doctor, pharmacist, or nurse before using this medicine if you have any of the following conditions:

- have recently (within 3 months) had a **myocardial infarction** or **stroke**
- **chest pain** (unstable angina) or angina at rest
- **heart disease** that affects the heart rate or heart rhythm
- **hypertension** that is not being treated with medication
- severe or moderate **liver disease**
- severe **kidney disease**
- **diabetes**
- overactive **thyroid**
- tumor in **the adrenal medulla** (pheochromocytoma)
- **gastric ulcers** or **duodenal ulcers**
- **inflammation of the esophagus**
- history of **epilepsy** or **seizures**

However, the risk of continuing to smoke is always a greater danger than the use of Nicorette. Chewing gum can get stuck in dentures and bridges and occasionally cause damage to them.

### Children and adolescents

Adolescents between the ages of 12 and 17 should only use Nicorette chewing gum if they have been prescribed it by a healthcare professional. Nicorette chewing gum should not be used by children under 12 years of age.

Nicotine doses tolerated by adult smokers during treatment may induce severe symptoms of poisoning in children and may be fatal. It is therefore important that Nicorette be kept out of the sight and reach of children at all times.

### Other medicines and Nicorette

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is especially important if you are taking medicines that contain

- **theophylline** to treat asthma
- **tacrine** for Alzheimer's disease
- **clozapine** for schizophrenia
- **ropinirole** to treat Parkinson's disease

### Used of Nicorette chewing gum with food and drink

You should not eat or drink with the chewing gum in your mouth. Concomitant use of coffee, juices, or soft drinks can reduce the absorption of nicotine. These drinks should be avoided 15 minutes before using the chewing gum.

### Pregnancy, breast-feeding, and fertility

It is very important to quit smoking during pregnancy because smoking can impair the growth of the fetus. Smoking can also cause the baby to be born prematurely or lead to miscarriage. Ideally, you should be able to quit smoking without using nicotine-containing medicines. If you are unable to do this, Nicorette should only be used after consulting the healthcare professional who is looking after your pregnancy, your doctor, or a healthcare professional who specializes in smoking cessation.

Nicorette chewing gum should be avoided during breast-feeding, as nicotine passes into breast milk and can affect your baby. If your healthcare professional has advised you to use Nicorette, the gum should be taken immediately after breast-feeding.

Smoking increases the risk of infertility in women and men. The effects of nicotine on fertility are unknown.

### Driving and using machines

No effects on the ability to drive or operate machinery have been observed.

### Nicorette 2 mg and 4 mg contain

- **sorbitol (2 mg: 190 mg/chewing gum, 4 mg: 179 mg/chewing gum)** which is a source of fructose. If you have an intolerance to certain sugars, or if you have been diagnosed with hereditary fructose intolerance, a rare inherited disorder that prevents you from breaking down fructose, talk to your doctor before using this medicine.
- **less than 0.7 mg butylhydroxytoluene (E321) per chewing gum** from the gum base, which may cause local skin reactions (e.g. contact eczema) or be irritating to the eyes and mucous membranes.
- **flavoring with cinnamaldehyde, cinnamon alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, and linalol.** These substances can cause allergic reactions.
- less than 1 mmol (23 mg) **sodium** per chewing gum, i.e. is practically “sodium-free.”
- 0.616 mg **alcohol (ethanol)** per chewing gum. This low amount of alcohol comes from a flavoring agent and produces no noticeable effects.

### Nicorette Peppermint 2 mg and 4 mg contain

- **Xylitol (2 mg: 608 mg/chewing gum, 4 mg: 596 mg/chewing gum)**, which may have a laxative effect. Caloric value: 2.4 kcal/g xylitol, which is equivalent to 1.5 kcal and 1.4 kcal respectively per chewing gum (Nicorette Peppermint 2 mg and 4 mg, respectively).
- **less than 0.6 mg butylhydroxytoluene (E321)** per chewing gum from the gum base, which may cause local skin reactions (e.g. contact eczema) or be irritating to the eyes and mucous membranes.
- less than 1 mmol (23 mg) **sodium** per chewing gum, i.e. is practically “sodium-free.”

### Nicorette Fruitmint 2 mg and 4 mg contain

- **xylitol (2 mg: 592 mg/chewing gum, 4 mg: 580 mg/chewing gum)**, which may have a laxative effect. Caloric value: 2.4 kcal/g xylitol, which is equivalent to 1.4 kcal per chewing gum (Nicorette Fruitmint 2 mg and 4 mg).
- **less than 0.6 mg butylhydroxytoluene (E321)** per chewing gum from the gum base, which may cause local skin reactions (e.g. contact eczema) or be irritating to the eyes and mucous membranes.
- less than 1 mmol (23 mg) **sodium** per chewing gum, i.e. is practically “sodium-free.”

## 3. How to use Nicorette

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist, or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

Medicated chewing gum 2 mg: can be used alone or in combination with Nicorette transdermal patches.

Medicated chewing gum 4 mg: used alone.

It is important to have the right chewing technique. Nicorette should be chewed *slowly* and with pauses during which the chewing gum is allowed to *rest* in the mouth before continuing to chew. Otherwise, you run the risk of heartburn and hiccups.

The nicotine effects only set in after a few minutes. Therefore, you can't expect the same quick gratification as with smoking. The risk of poisoning is small if you accidentally swallow the chewing gum, as the nicotine is then released slowly and incompletely.

### **Treatment with Nicorette chewing gum alone**

Chewing gum strength should be chosen based on your nicotine addiction. If you smoke more than 20 cigarettes daily or if you have previously failed with Nicorette 2 mg, 4 mg should be chosen. In other cases, 2 mg should be used.

The instructions for how to take Nicorette chewing gum depend on whether you:

- a) quit smoking abruptly
- b) quit smoking with tapering (smoking reduction)

#### *a) Abrupt cessation of smoking*

Nicorette chewing gum should be taken when cigarettes would normally be smoked or if the urge to smoke arises. At the beginning of treatment, 1 chewing gum can be taken every one to two hours. Sufficient chewing gum should be taken every day. The dosage is individual based on your nicotine addiction. In most cases, 8-12 chewing gums daily is sufficient. To maximize the chances of success, it is important not to underdose. No more than 24 chewing gums daily should be used.

The duration of treatment is individual. Normally, treatment should last at least 3 months. After that, the nicotine dose is gradually reduced. Treatment should be discontinued once the dose has been reduced to 1-2 chewing gums daily.

Regular use of Nicorette chewing gum for longer than 12 months is not normally recommended.

In some cases, a longer treatment period may be necessary to avoid relapse to smoking.

Leftover chewing gum should be saved, as the urge to smoke can arise suddenly.

#### *b) Quitting smoking with tapering (smoking reduction)*

Nicorette chewing gum is used between smoking periods to prolong smoke-free intervals and with the aim of reducing smoking as much as possible. If a reduction in the number of cigarettes daily has not been achieved after 6 weeks, professional help should be sought. Attempts to quit smoking should be made as soon as you feel prepared, but no later than 6 months after starting treatment. Follow the instructions on quitting smoking abruptly. If it is not possible to make a serious attempt to quit smoking within 9 months of the start of treatment, seek professional assistance (such as the "Quit smoking line" phone number 020-84 00 00).

Regular use of Nicorette chewing gum for longer than 12 months is not normally recommended.

In some cases, a longer treatment period may be necessary to avoid relapse to smoking.

Leftover chewing gum should be saved, as the urge to smoke can arise suddenly.

### **Treatment with Nicorette 2 mg chewing gum in combination with Nicorette transdermal patches**

If you have a high nicotine dependence, experience nicotine cravings despite the use of nicotine replacement therapy, or if you have been unsuccessful with a nicotine replacement therapy alone, you can use Nicorette transdermal patches together with Nicorette 2 mg chewing gum for quick relief of nicotine cravings.

**IMPORTANT** Read the package leaflet for Nicorette transdermal patch (included in this package) before use.

#### *Initial combination therapy*

You should quit smoking completely during the combination treatment.

A 25 mg/16 hour transdermal patch is applied in the morning and removed at bedtime for 8 weeks.

Use Nicorette 2 mg chewing gum with the patch as follows:

Have a chewing gum when you feel the urge to smoke even though you are using Nicorette patches. The usual dose is 5-6 chewing gums daily. Use no more than 24 chewing gums daily.

After 8 weeks, gradually reduce the nicotine dose according to one of the following two options:

*Weaning from nicotine medication – option 1*

After the first 8 weeks, use patches with a lower strength:

1 patch 15 mg/16 hours daily for 2 weeks followed by 1 patch 10 mg/16 hours daily for 2 weeks.

At the same time, use the same amount of chewing gum (2 mg) as during the initial treatment.

After that, gradually reduce the number of chewing gums. Do not use chewing gum for longer than 12 months from the start of treatment.

*Weaning from nicotine medication - option 2*

Discontinue the use of patches after the first 8 weeks. After that, gradually reduce the number of chewing gums. Do not use chewing gum for longer than 12 months from the start of treatment.

**Course of combination therapy in table form**

<b>Period</b>	<b>Patch</b>	<b>Chewing gum 2 mg</b>
Weeks 1-8	1 patch 25 mg/16 hours daily	As needed. The usual dose is 5-6 chewing gums daily (max 24)
<b>Weaning from nicotine medication – option 1</b>		
Week 9-10	1 patch 15 mg/16 hours daily	Continue to use chewing gum as needed
Week 11-12	1 patch 10 mg/16 hours daily	Continue to use chewing gum as needed
Up to 12 months	---	Gradually reduce the number of chewing gums
<b>Weaning from nicotine medication – option 2</b>		
Up to 12 months	---	Continue to gradually reduce the number of chewing gums

**If you take more Nicorette than you should**

Nicotine overdose can occur if you smoke while using Nicorette gum.

If you have ingested too much medicine or if, for example, if a child has accidentally ingested the medicine, contact a doctor, hospital, or the Poison Information Center (tel. 112) for risk assessment and advice.

Nicotine doses that are tolerated by adult smokers undergoing treatment can cause severe symptoms of intoxication and potentially fatal outcome in children.

Symptoms of overdose include nausea, vomiting, increased salivation, abdominal pain, diarrhea, sweating, headache, dizziness, hearing change, and a pronounced feeling of weakness. At high doses, these symptoms may be followed by low blood pressure, weak and irregular pulse, difficulty breathing, extreme fatigue, circulatory collapse, and general seizures.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

**4. Possible side effects**

**Symptoms associated with quitting smoking (withdrawal symptoms)**

Some of the side effects that you experience when you quit smoking may be withdrawal symptoms, which occur due to reduced nicotine intake.

**These symptoms include:**

- Irritation, aggression, impatience or frustration
- Anxiety, restlessness, or difficulty concentrating
- Waking up at night or sleep disturbances
- Increased appetite or weight gain
- Depression
- Urge to smoke (craving)
- Lowered heart rate
- Bleeding gums or mouth ulcers
- Dizziness or a feeling as if about to faint
- Cough, sore throat, blocked or runny nose
- Constipation

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Nicorette can cause the same side effects as nicotine given in other ways. The side effects generally depend on the size of the dose you are taking.

Irritation of the mouth and throat may be experienced, but most users adapt to this with continuous use.

***If you notice that you have any of the following serious and rare side effects, stop taking Nicorette and seek medical attention immediately.***

***Symptoms of angioedema (may affect up to 1 in 1,000 users):***

- swelling of the face, tongue, or throat
- difficulty swallowing
- hives, skin rash, and difficulty breathing

**Very common side effects** (may affect more than 1 in 10 users):

- Headache
- Cough, throat irritation
- Hiccups, nausea

**Common side effects** (may affect up to 1 in 10 users):

- Local effects such as burning sensation, inflammation in the mouth, altered sense of taste
- Dry mouth or increased salivation
- Stomach upset or pain in the stomach
- Vomiting, flatulence, or diarrhea
- Fatigue
- Hypersensitivity (allergy)
- Stinging sensation

**Uncommon side effects** (may affect up to 1 in 100 users):

- Nasal congestion, sneezing
- Wheezing breath (bronchospasm), difficulty breathing (dyspnea), tightness in the throat
- Redness of the skin (flushing), increased sweating
- Tingling in the mouth, inflammation of the tongue, damage to the oral mucosa, changes in voice, pain in the mouth and throat, belching
- Heart palpitations (an abnormal experience of your heartbeat), increased heart rate, high blood pressure
- Skin rash (including hives) and/or itching

- Abnormal dreams
- Discomfort and pain in the chest
- Feeling weak, feeling unwell
- Pain in the jaw muscle

**Rare side effects** (may affect up to 1 in 1,000 users):

- Difficulty swallowing, decreased sensitivity in the mouth
- Nausea
- Abnormal heart rhythm (atrial fibrillation)

**Reported** (affects an unknown number of users):

- Blurred vision, increased tear production (lacrimation)
- Dryness in the throat, discomfort in the stomach, pain in the lips
- Redness of the skin
- Allergic reaction with swelling of the face and mouth (angioedema or anaphylaxis)
- Tense jaw
- Epileptic attack (may involve seizures)

### **Reporting of adverse reactions**

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Swedish Medical Products Agency  
Box 26  
751 03 Uppsala  
Website: [www.lakemedelsverket.se](http://www.lakemedelsverket.se)

## **5. How to store Nicorette**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Nicorette contains**

Nicorette chewing gum is sugar-free, available in several different flavors and in two strengths, 2 mg and 4 mg.

#### *Nicorette 2 mg*

- The active substance is nicotine. One chewing gum contains 2 mg of nicotine in the form of nicotine resinate.
- The other ingredients are: 190 mg sorbitol, chewing gum base (contains butylhydroxytoluene E 321), sodium bicarbonate, sodium carbonate (anhydrous), flavoring (contains traces of

ethanol, cinnamaldehyde, cinnamon alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, and linalol), glycerol, and talc.

*Nicorette 4 mg*

- The active substance is nicotine. One chewing gum contains 4 mg of nicotine in the form of nicotine resinate.
- The other ingredients are: 179.3 mg sorbitol, chewing gum base (contains butylhydroxitoluene E 321), sodium carbonate (anhydrous), flavoring (contains traces of ethanol, cinnamaldehyde, cinnamon alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, and linalol), glycerol, quinoline yellow (E104), and talc.
- See section 2 “**Nicorette 2 mg and 4 mg contain**” for more information.

*Nicorette Fruitmint 2 mg*

- The active substance is nicotine. One chewing gum contains 2 mg of nicotine in the form of nicotine resinate.
- The other ingredients are: 591.5 mg xylitol, chewing gum base (contains butylhydroxytoluene E 321), sodium bicarbonate, sodium carbonate (anhydrous), magnesium oxide (light), acesulfame potassium, flavorings (peppermint oil, levomenthol, tuttifrutti), hypromellose, sucralose, polysorbate 80, acacia gum, titanium dioxide (E 171), carnauba wax, and talc.

*Nicorette Fruitmint 4 mg*

- The active substance is nicotine. One chewing gum contains 4 mg of nicotine in the form of nicotine resinate.
- The other ingredients are: 579.5 mg xylitol, chewing gum base (contains butylhydroxytoluene E 321), sodium carbonate (anhydrous), magnesium oxide (light), acesulfame potassium, flavorings (peppermint oil, levomenthol, tuttifrutti), hypromellose, sucralose, polysorbate 80, acacia gum, titanium dioxide (E 171), quinoline yellow (E 104), carnauba wax, and talc.
- See section 2 “**Nicorette Fruitmint 2 mg and 4 mg contain**” for more information.

*Nicorette Peppermint 2 mg*

- The active substance is nicotine. One chewing gum contains 2 mg of nicotine in the form of nicotine resinate.
- The other ingredients are: 608 mg xylitol, chewing gum base (contains butylhydroxytoluene E 321), sodium bicarbonate, sodium carbonate (anhydrous), magnesium oxide (light), acesulfame potassium, flavorings (peppermint oil, levomenthol), acacia gum, titanium dioxide (E 171), carnauba wax, and talc.

*Nicorette Peppermint 4 mg*

- The active substance is nicotine. One chewing gum contains 4 mg of nicotine in the form of nicotine resinate.
- The other ingredients are: 596 mg xylitol, chewing gum base (contains butylhydroxytoluene E 321), sodium carbonate (anhydrous), magnesium oxide (light), acesulfame potassium, flavorings (peppermint oil, levomenthol), acacia gum, titanium dioxide (E 171), quinoline yellow (E 104), carnauba wax and talc.
- See section 2 “**Nicorette Peppermint 2 mg and 4 mg contain**” for more information.

## What Nicorette looks like and contents of the pack

### Nicorette

2 mg: light beige square

4 mg: light yellow square

### Nicorette Peppermint, Nicorette Fruit Mint

2 mg: whitish, coated chewing gum, approx. 15 x 15 x 6 mm

4 mg: cream-colored, coated chewing gum, approx. 15 x 15 x 6 mm



Nicotine (as nicotine resinate)  
medicated chewing gum 4mg  
(McNeil Sweden AB) TD002

WHOPAR part 3  
Suppliers submission of the  
SRA approved text

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2 mg

Nicorette Peppermint: 10, 12, 15, 24, 30, 48, 90, 96, 105, 204, 210 pcs in blister pack

Nicorette Fruitmint: 12, 15, 24, 30, 48, 90, 96, 105, 204, 210 pcs in blister pack

Nicorette: 30, 105, 210 pcs in blister pack

4 mg

Nicorette Peppermint, Nicorette Fruitmint: 12, 15, 24, 30, 48, 90, 96, 105, 204, 210 pcs in blister pack

Nicorette: 30, 105, 210 pcs in blister pack

All packages contain a leaflet.  
Not all pack sizes may be marketed.

**Marketing authorization holder:**

McNeil Sweden AB, Solna  
Tel.: 08 – 503 385 00  
[Consumer-se@kenvue.com](mailto:Consumer-se@kenvue.com)

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