



- Freshmint
- 2 & 4 mg medicated chewing gum
- Freshfruit
- 2 & 4 mg medicated chewing gum
- Nicotine

Read this leaflet carefully. It contains important information for you.

It is essential to use Nicorette medicated chewing gum with caution in order to achieve best results. Save this patient information leaflet; you may need to read it again. Ask at the pharmacy if you need more information or advice. If any undesirable effects become more severe or you notice undesirable effects that are not mentioned in this information leaflet, consult a doctor or the pharmacist.

This patient information leaflet contains the following information:

1. What Nicorette medicated chewing gum is and what it is used for.
2. Before taking Nicorette medicated chewing gum.
3. How to take Nicorette medicated chewing gum.
4. Possible undesirable effects.
5. How Nicorette medicated chewing gum should be stored.
6. Other information.

What is Nicorette medicated chewing gum? Nicorette Freshfruit 2 mg

The active substance is nicotine. One piece of chewing gum contains 2 mg of nicotine in the form of nicotine resinates.

Other ingredients are: 591.5 mg xylitol, chewing gum base (contains butylated hydroxytoluene E 321), sodium hydrogen carbonate, sodium carbonate (anhydrous), magnesium oxide (light), acesulphame potassium, flavours (peppermint oil, levomenthol, tutti frutti), hypromellose, sucralose, polysorbate 80, acacia gum, titanium dioxide (E 171), carnauba wax and talc.

Nicorette Freshfruit 4 mg

The active substance is nicotine. One piece of chewing gum contains 4 mg of nicotine in the form of nicotine resinates. Other ingredients are: 579.5 mg xylitol, chewing gum base (contains butylated hydroxytoluene E 321), sodium carbonate (anhydrous), magnesium oxide(light), acesulphame potassium, flavours (peppermint oil, levomenthol, tutti frutti), hypromellose, sucralose, polysorbate 80, acacia gum, titanium dioxide (E171), quinoline yellow (E104), carnauba wax and talc.

Nicorette Freshmint 2 mg

The active substance is nicotine. One piece of chewing gum contains 2 mg of nicotine in the form of nicotine resinates. Other ingredients are: 608 mg xylitol, chewing gum base (contains butylated hydroxytoluene E 321), sodium hydrogen carbonate, sodium carbonate (anhydrous), magnesium oxide (light), acesulphame potassium, flavours (peppermint oil, levomenthol), acacia gum, titanium dioxide (E 171), carnauba wax and talc.

Nicorette Freshmint 4 mg

The active substance is nicotine. One piece of chewing gum contains 4 mg of nicotine in the form of nicotine resinates. Other ingredients are: 596 mg xylitol, chewing gum base (contains butylated hydroxytoluene E 321), sodium carbonate (anhydrous), magnesium oxide(light), acesulphame potassium, flavours (peppermint oil, levomenthol), acacia gum, titanium dioxide (E 171), quinoline yellow (E 104), carnauba wax and talc.

1. WHAT NICORETTE MEDICATED CHEWING GUM IS AND WHAT IT IS USED FOR?

Nicorette is one of a group of products that are used to help you stop smoking.

The nicotine in Nicorette medicated chewing gum alleviates the craving for nicotine and withdrawal symptoms when you stop smoking. Thus, it helps counteract relapse into smoking among smokers who are motivated to quit or facilitates reduction of smoking among smokers who cannot or are unwilling to stop smoking. When you suddenly stop supplying the body with nicotine from tobacco you suffer various forms of discomfort, known as withdrawal symptoms. With the aid of Nicorette medicated chewing gum you can prevent, or at least, reduce these discomforts by continuing to supply the body with a small quantity of nicotine for a transitional period. When you chew Nicorette, nicotine is slowly released and absorbed via the oral cavity. Unlike cigarettes, Nicorette medicated chewing gum contains no harmful tar or carbon monoxide. Advice and support normally improve the chance of success.

2. BEFORE TAKING NICORETTE MEDICATED CHEWING GUM

Do not take Nicorette medicated chewing gum if:

- You are allergic (hypersensitive) to nicotine or any of the other excipients in Nicorette medicated chewing gum;
- You have severe heart disease (e.g. unstable angina pectoris, serious arrhythmia);
- You have recently (within the last 3 months) suffered a heart attack or stroke.

Take special care with Nicorette medicated chewing gum Consult your Doctor if:

- You have severe cardiovascular disease, such as heart or circulation problems including heart failure, stable angina or occlusive peripheral artery disease.
- You have untreated high blood pressure.
- You have a stomach ulcer.
- You have an overactive thyroid gland.
- You are diabetic (you may require lower doses of insulin as a result of smoking cessation).
- You have been diagnosed as having a tumour of the adrenal glands (pheochromocytoma).
- You have severe/moderate liver or severe kidney disease.
- You are under the age of 18 years.

However the risk in continued smoking always constitutes a greater hazard than use of Nicorette medicated chewing gum. Young people under 18 should only use Nicorette medicated chewing gum if prescribed by a doctor. Nicorette medicated chewing gum should not be used by nonsmokers.

The chewing gum may adhere to dentures and dental bridges and in rare cases damage them.

Using other medicines:

Tell your doctor or pharmacist if you are taking or have recently taken other medication, even non-prescription drugs. This is particularly important if you are using drugs containing theophylline, tacrine, clozapine or ropinirol. Patients with diabetes mellitus may require lower doses of insulin as a result

of smoking cessation. When you use the chewing gum there will be a reduction in the amount of nicotine in your body and with time this will get lower still compared with when you smoked. This change can affect the way your body responds to some medicines.

Using Nicorette medicated chewing gum with food and drink

You should not eat or drink with the chewing gum in the mouth. Simultaneous consumption of coffee, fruit juices or carbonated soft drinks may reduce the absorption of nicotine. These drinks should be avoided for the 15 minutes before the chewing gum is used.

Pregnancy and breast-feeding

It is very important to stop smoking during pregnancy as smoking may lead to poor foetal growth. It may also lead to premature birth or even miscarriage. The best thing is if you can stop smoking without using nicotine products at all. If you cannot manage this, Nicotine medicated chewing gum should only be used after you have taken advice from your doctor.

Nicorette medicated chewing gum should be avoided during lactation as nicotine passes over in breast milk and may affect your child.

Effect on ability to drive and use machines No effect on the ability to drive a car or operate machines has been observed.

Important information about some of the ingredients of Nicorette medicated chewing gum. Nicorette Freshmint and Nicorette Freshfruit contain xylitol, which may have a laxative effect.

Calorific value: 2.4 kcal/g xylitol, which is equivalent to 1.4 kcal per piece of chewing gum (Nicorette Freshfruit 2 mg and 4 mg) and 1.5 kcal or 1.4 kcal per piece (Nicorette Freshmint 2 mg and 4 mg respectively).

3. HOW TO TAKE NICORETTE MEDICATED CHEWING GUM

Always take Nicorette medicated chewing gum as stated in the patient information leaflet. You should always consult your doctor or the pharmacy staff if you are uncertain. Medicated chewing gum 2 mg: can be used alone or in combination with Nicorette transdermal patches.

Medicated chewing gum 4 mg: is used alone.

The correct chewing method is important. 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 risk heartburn and hiccups. The nicotine effects only arise after a few minutes. Therefore the same rapid satisfaction cannot be expected as from smoking. The risk of poisoning is small if the chewing gum should happen to be swallowed because the nicotine is then released slowly and incompletely.

Treatment with Nicorette medicated chewing gum alone

The strength of the chewing gum should be chosen on the basis of your nicotine dependency. If you smoke more than 20 cigarettes per day or if you have previously been unsuccessful with Nicorette 2 mg, you should choose 4 mg. In other cases 2 mg should be used.

At the commencement of treatment 1 piece of chewing gum may be taken every hour or every 2 hours. In most cases 8-12 pieces of chewing gum per day are enough. No more than 24 pieces per day should be used.

Smoking cessation:

The treatment period is individual. In the normal case the treatment ought to continue for at least 3 months. The nicotine dose is then reduced successively. The treatment should be discontinued when the dose has been reduced to 1-2 pieces of chewing gum per day.

Smoking reduction:

Nicorette chewing gum is used between smoking periods in order to prolong smoking-free intervals and with a view to reducing smoking as much as possible. If a reduction in the number of cigarettes per day has not been achieved after 6 weeks,



What happens if you take too large dose of Nicorette medicated chewing gum?

Over dosage with nicotine may occur if you smoke while using Nicorette medicated chewing gum.

If you take too much nicotine or if a child accidentally uses Nicorette medicated chewing gum you should immediately contact a doctor or hospital for assessment of the risk and advice. Symptoms of over dosage are nausea, increased salivation, abdominal pain, diarrhea, sweating, headache, dizziness, disturbed hearing and prostration. Consult your doctor or the pharmacy staff if you have any questions concerning the use of this product.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nicorette medicated chewing gum can cause side effects although not all users experience them.

Nicorette medicated chewing gum may cause the same side effects as nicotine given by another route. The side effects are usually dose-dependent.

The most common side effects (occurring in more than 1 user in 100 and fewer than 1 user in 10) especially during the first few weeks are:

- * dryness or irritation of the mouth and throat

Other common side effects (occurring in more than 1 in 100 users and in fewer than 1 in 10 users) are:

- * dizziness
- * vomiting
- * headache
- * hiccups
- * nausea
- * soreness of the jaw joint

Less common side effects (occurring in more than 1 in 1,000 users and in fewer than 1 in 100 users) are:

- * palpitations
- * skin rash

Rare side effects (occurring in more than 1 in 10,000 users and in fewer than 1 in 1,000 users) are:

- * atrial fibrillation
- * allergic reactions such as angioedema

Contact your doctor if the undesirable effects continue.

Certain symptoms, such as dizziness, headache and insomnia, may be regarded as withdrawal symptoms during smoking cessation and depend on too low an administration of nicotine. Aphthous mouth ulcers may arise when giving up smoking, but the connection with nicotine treatment is unclear.

If any undesirable effects become more severe or you notice undesirable effects that are not mentioned in this information leaflet, consult a doctor or the pharmacist.

5. HOW NICORETTE MEDICATED CHEWING GUM SHOULD BE STORED

Keep out of sight and reach of children.

Do not store at above 25°C.

Use before the final date shown on the carton. The final date is the last day of the month shown. Unless instructed otherwise, don't dispose of unused gums by emptying them into your sink, toilet or storm drain. Consult the pharmacy on disposal of unwanted gums. These precautions are necessary in order to protect



the environment.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorization Holder.

Appearance of product and pack sizes Nicorette Freshmint, Nicorette Freshfruit

- 2 mg: whitish, coated chewing gum, approx. 15 x 15 x 6 mm
- 4 mg: cream-coloured, coated chewing gum, approx. 15 x 15 x 6 mm

Pack sizes: 2 mg

Nicorette Freshmint: 10, 12, 15, 24, 30, 48, 90, 96, 105, 204, 210 pieces in blister pack.

Nicorette Freshfruit: 12, 15, 24, 30, 48, 90, 96, 105, 204, 210 pieces in blister pack.

4 mg

Nicorette Freshmint, Nicorette Freshfruit:

12, 15, 24, 30, 48, 90, 96, 105, 204, 210 pieces in blister pack.

All packages contain a patient information leaflet. It is possible that not all package sizes will be marketed.

Manufacturer

McNeil AB, Helsingborg, Sweden.

Marketing Authorization Holder

McNeil Sweden AB 169 90 Solna, Sweden

This is a Medicament

- * Medicament is a product, which affects our health and its consumption contrary to instructions, is dangerous for you.
- * Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- * The doctor and pharmacist are the experts in medicines, their benefits and risks.
- * Do not by yourself interrupt the period of treatment prescribed.
- * Do not repeat the same prescription without consulting your doctor.
- * Keep all medicaments out of reach of children.

Council of Arab Health Ministers – Union of Arab Pharmacists.

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professional help ought to be sought. Attempts to stop smoking ought to be made as soon as the smoker feels ready, but in any case not later than 6 months after the start of treatment. If it is not possible to make a serious attempt to stop smoking within 9 months after the start of treatment professional help should be sought.

Regular use of Nicorette chewing gum for longer than 1 year is not normally recommended. Some ex-smokers may however need treatment for longer in order not to return to smoking. Unused chewing gum should be saved, as the craving to smoke may arise suddenly.

Treatment with Nicorette 2 mg medicated chewing gum in combination with Nicorette transdermal patches:

If treatment with Nicorette medicated chewing gum alone has been unsuccessful or if you wish to reduce your use of chewing gum because of local side effects you can use Nicorette transdermal patches together with Nicorette 2 mg medicated chewing gum.

NOTE! Read the patient information leaflet for Nicorette transdermal patches (enclosed in the container) before use. Initial treatment One 15 mg/16 hour transdermal patch is applied every morning and removed on going to bed for a period. This is done for 6-12 weeks.

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

Use at least 4 pieces of chewing gum (2 mg) per day. In most cases 5-6 pieces of chewing gum are enough. Use a maximum of 24 pieces of chewing gum per day. After 6-12 weeks you gradually reduce the nicotine dose in accordance with one of the following two alternatives:

• Cessation alternative 1:

After the first 6-12 weeks you use patches of lower strength: 1 patch 10 mg/16 hrs daily for 3-6 weeks followed by 1 patch 5 mg/16 hrs daily for a further 3-6 weeks. At the same time use as many pieces of chewing gum (2 mg) as during the initial treatment. Then reduce the number of pieces of chewing gum gradually. Do not use the chewing gum for longer than 12 months from the start of treatment.

• Cessation alternative 2:

Stop using the patches after the first 6-12 weeks. Then gradually reduce the number of pieces of chewing gum. Do not use the chewing gum for longer than 12 months from the start of treatment.

Course of combination treatment in tabular form:

Initial treatment		
Period	Patches	Chewing gum 2 mg
First 6-12 weeks	1 patch 15 mg/16 hours daily	As needed 5-6 pieces per day is recommended
Cessation – alternative 1		
Next 3-6 weeks	1 patch 10 mg/16 hours daily	Continue to use the chewing gum as needed
Following 3-6 weeks	1 patch 5 mg/16 hours daily	Continue to use the chewing gum as needed
Up to 12 months	---	Reduce the number of pieces gradually
Cessation – alternative 2		
Up to 12 months	---	Continue to reduce the number of pieces gradually