

Package leaflet: information for the user

Nicorette® Sugar-free 2 mg gum
Nicorette® Sugar-free 4 mg gum
Nicorette® Sugar-free Freshfruit 2 mg gum
Nicorette® Sugar-free Freshfruit 4 mg gum

Nicotine

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need it again later.
- Do you have any questions? Then contact your pharmacist.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.
- Do you still experience after 6 months difficulties in quitting smoking? Then contact your doctor.

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1. What is Nicorette gum and what is this medicine used for?used?

Nicorette is a flavored sugar-free gum with nicotine as active ingredient.

The nicotine in Nicorette belongs to the group of withdrawal aids. Nicorette Sugar-Free 2 mg and Nicorette Sugar-Free Freshfruit 2 mg are used to combat the strong craving for nicotine that people can experience when quitting smoking or reducing it. When this craving is very strong, you can use Nicorette Sugar-Free 4 mg and Nicorette Sugar-Free Freshfruit 4 mg. When you chew the gum, the nicotine is slowly released and absorbed into the body through the mouth. T

his nicotine is enough this nicotine is enough reduce the craving for smoking. Unlike tobacco smoke, Nicorette does not contain harmful tar or carbon monoxide. to reduce the need to smoke. Unlike tobacco smoke, Nicorette does not contain harmful tar or carbon monoxide.

2. When should you not use this

medicine? do not use the drug?

- You are allergic to one of the substances in this medicine. You can find these substances in section 6 of this leaflet.
- You have a serious heart condition:
 - a recent heart attack;
 - arrhythmias;
 - a constricting, painful feeling in the chest (angina pectoris);
 - a so-called Prinzmetal angina.
- You have recently had a cerebral hemorrhage (stroke).
- You have an inflammation in the mouth, throat, or esophagus.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine. Completely stop smoking or smoke less when you start using Nicorette.

Stop completely with smoking or smoke less when you start using Nicorette.

doctor should evaluate whether you can use Nicorette: if you have a cardiovascular disease such as a rece

- if you have a cardiovascular disease such as a receheart attack, unstable or worsening angina pectoris, including Prinzmetal's angina, severe arrhythmias, uncontrolled hypertension, or have had a recent stroke: preferably you should quit smoking under supervision without nicotine replacement therapy. Contact your doctor or pharmacist before using this medicine if you suffer from angina pectoris, if you have recently had a bypass or balloon dilation of the coronary arteries, if you have any other heart disorder or if you have a vascular condition. if you have a vascular condition.
- you have diabetes: then your blood sugar level should be monitored more closely. if you have diabetes: then your blood sugar level must be monitored more closely.
- you have a kidney and liver condition: there is a chance of an increase in side effects. if you have a kidney and liver disorder: there is a chance of an increase in side effects.
- you have a tumor you have a tumor of the adrenal glands (pheochromocytoma) or an uncontrolled increased activity of the thyroid gland.
- you have gastrointestinal disorders (inflammation of the esophagus, stomach or duodenal ulcer): nicotine may worsen your symptoms. you have gastrointestinal disorders (inflammation of the esophagus, stomach or intestinal ulcer): nicotine can worsen your symptoms.
- you have had epilepsy or seizures in the past. Long-term use of Nicorette by ex-smokers is not recommended, as nicotineepilepsy or has had seizures.

considered addictive. Nicotine is a toxic substance, which appears to be well tolerated by the body. tea during nicotine replacement therapy.

If you have dentures, chewing gum may be a problem. The gum can stick to the dentures and in rare cases damage them.

Children and adolescents up to 18 years

Nicorette should not be administered to persons under 18 years without a doctor's prescription.

Nicorette should be kept out of reach of children be kept. Danger to children: nicotine doses tolerated by smokers can cause severe poisoning symptoms in childrenand be fatal. Nicotine products should not be stored in places where they can be handled or ingested by children.

Are you using any other medicines?

Are you using any other medicines besides Nicorette, have you done so recently or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medicines you can obtain without a prescription.

Smoking can affect the excretion of some medicines by the body. Stopping smoking, with or without nicotine replacement, can change the response of ex-smokers to concurrently used medicines. For example, when you use medicines like theophylline (used for asthma), tacrine (used for Alzheimer's disease), clozapine or olanzapine (used for schizophrenia), ropinirole (used for Parkinson's disease), imipramine, clomipramine or fluvoxamine (used for depression), flecainide (used for irregular heart rhythm) or pentazocine (a strong painkiller), stopping smoking can lead to an increase in the amount of medicine in your blood.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Pregnancy

Nicotine

Nicotine can have an effect on the unborn child. You should completely avoid nicotine during pregnancy. You must stop smoking when you are pregnant, especially stop smoking when you are pregnant, in case without the use of nicotine replacement products. Therefore, you should not use during pregnancy, except for women who cannot quit smoking without nicotine replacement therapy. The danger of continuing to smoke during pregnancy may pose a greater risk to the unborn child than the use of nicotine replacement products under expert guidance. First consult your doctor if you wish to use Nicorette during pregnancy.

Breastfeeding

Nicotine passes into breast milk. It is possible that the infant may be affected by this. Therefore, you should avoid using nicotine while breastfeeding. The danger of continuing to smoke may pose a greater risk to the child than the use of nicotine replacement products in a smoking cessation program under guidance. If you are heavily dependent on nicotine and wish to breastfeed, the use of Nicorette should only be on the advice of your doctor. Nicorette chewing gum should then be used as soon as possible after feeding. The time between using Nicorette gum and breastfeeding should be as long as possible to be and in any case not less than 2 to 3 hours. Also, the strength of the used Nicorette gum should be as low as possible to be.

Fertility

Both in women and in men, smoking increases the risk of infertility. In humans and animals, it has been shown that nicotine has adverse effects on sperm quality. In animals, reduced fertility has also been demonstrated.

Driving ability and the use of machines

Nicorette has no or negligible influence on driving ability or the use of machines.

Nicorette Sugar-Free 2 mg and Nicorette Sugar-Free 4 mg contain sorbitol (E420). Nicorette Sugar-Free 2 mg contains 190 mg sorbitol per gum and Nicorette Sugar-Free 4 mg contains 179 mg sorbitol per gum. Sorbitol is a source of fructose. If your doctor has told you that you cannot tolerate certain sugars or if you have been diagnosed with hereditary fructose

intolerance (a rare hereditary condition where a person cannot break down fructose), contact your doctor before you are given this medicine.

Nicorette 2 mg and 4 mg contain flavorings with cinnamal, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, linalool. These substances can cause allergic reactions.

Nicorette Sugar-Free 2 mg and 4 mg gum contain 0.616 mg alcohol (ethanol) per gum. There is a small amount of alcohol in this medicine. This is so little that you will not notice it.

Nicorette Sugar-Free and Nicorette Sugar-Free Freshfruit contain less than 1 mmol sodium (23 mg) per gum, which means it is essentially 'sodium-free'.

The gum base contains butylated hydroxytoluene (E321), an antioxidant. This excipient can locally cause skin reactions (e.g., contact dermatitis), or irritation to the eyes and mucous membranes.

3. How do you use this medicine?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

STOP SMOKING

1. Stop smoking completely from the first day.
2. You take one Nicorette gum when you feel the need to smoke. Highly dependent smokers are initially recommended to use Nicorette Sugar-Free (/Freshfruit) 4 mg to use (maximum 14 pieces of gum per day). Other smokers are recommended to use the 2 mg gum to use (maximum 14 pieces of gum per day).
3. Chew slowly, with regular pauses.
After about 30 minutes of intermittent chewing, all available nicotine is released from the gum. The effects of nicotine are only noticed after a few minutes; the rapid satisfaction that occurs with smoking is therefore not to be expected.
The use of acidic drinks such as coffee or soft drinks should be avoided for 15 minutes before and during chewing. These drinks affect the absorption of nicotine in the oral cavity.
Slow chewing promotes optimal absorption of nicotine by the oral mucosa. Swallowing saliva should therefore be minimized.
4. Nicorette has a special strong taste, which may seem a bit strange at first can seem. You will quickly get used to it.
5. The risk of to start smoking again and, is highest during the first 3 to 4 months. Therefore, do not stop using Nicorette quickly during this critical period. Nicorette
6. can only help. Quitting smoking permanently will always require your personal commitment. Advice and support improve the chance of success. on success.
7. pocket . has.
keep your cigarettes stored.
8. Gradually reduce the number of gums per day.
The duration of the treatment is individual. It is recommended after a treatment of about three months, to gradually reduce the use of Nicorette. When you are using only 1-2 gums daily, you can stop the treatment. Uninterrupted use of Nicorette for more than one year is not recommended.

9. Keep some spare gums on hand as the urge to smoke can suddenly return.
10. Keep your pharmacist or doctor regularly informed. They can give you advice.

SMOKE LESS

1. Replace as many as possible your cigarette with a gum.
The gum should be used as soon as there is an urge to smoke and to keep the smoke-free period as long as possible. This reduces the number of cigarettes. Strongly dependent smokers are initially recommended Nicorette Sugar-Free (/Freshfruit) 4 mg to use (maximum 14 pieces of gum per day). Other smokers are recommended the 2 mg gum to use (maximum 14 pieces of gum per day).
2. Chew slowly, with regular pauses.
After about 30 minutes of intermittent chewing, all available nicotine has been released from the gum. You will only notice the effects of nicotine after a few minutes; the quick satisfaction that occurs with smoking cannot be expected.
The use of acidic drinks such as coffee or soft drinks should be avoided for 15 minutes before and during chewing. These drinks affect the absorption of nicotine in the oral cavity.
Slow chewing promotes optimal absorption of nicotine by the oral mucosa. Swallowing saliva should therefore be minimized.
3. Nicorette has a special strong taste, which may seem a bit strange at first can seem. You will quickly get used to it.
4. Reduce the cigarette consumption until you completely can stop.
5. Nicorette can only help. Quitting smoking for good will always your personal commitment require. Advice and support improve the chance of success.
6. Make sure you always have a few pieces of gum in pocket have.
Place them in all the places where you previously your cigarettes stored.
7. Gradually reduce the number of gums per day.
When you are using only 1-2 pieces of gum daily, you can stop the treatment.
8. Keep some spare gums on hand as the urge to smoke can suddenly return.
9. Keep your pharmacist or doctor regularly informed. They can give you advice.

Use in children and adolescents up to 18 years

Nicorette should not be administered to persons under 18 years without a medical prescription from a doctor.

Have you used too much of this medicine?

If you are going to use Nicorette, you should completely stop smoking or reduce smoking. The symptoms of an overdose can occur when you chew a large number of gums at once or very quickly one after the other, or when you continue to smoke completely while using Nicorette. The risk of poisoning due to swallowing the gum is small, because the absorption in the body without chewing is slow and incomplete.

The symptoms of overdose are severe headache, dizziness, abdominal pain, nausea, vomiting, salivation, diarrhea, sweating, reduced hearing, and weakness. At high doses, these symptoms may be followed by too low blood pressure, weak and irregular pulse, breathing difficulties, exhaustion, sudden decrease in circulation, and general convulsions. If you have taken too much nicotine, or if a child has used a gum or if this is suspected, seek medical advice from your doctor or at an emergency department or a poison information center (phone: 112).
Keep out of reach of children.

Nicotine dosages tolerated by adult smokers during treatment can cause severe poisoning symptoms in children and can be fatal.

Have you forgotten to use this medicine too use?
Do not use a double dose to make up for a forgotten dose.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects?

Like any medicine can this medicine also have side effects. Not everyone will experience them. to deal with.

When quitting smoking, certain symptoms may occur such as a depressed mood, insomnia, irritability, frustration or anger, anxiety, difficulty concentrating, restlessness or impatience, slowed heart rate, increased appetite or weight gain, dizziness, cough, constipation, bleeding gums or mouth ulcers, or a cold. Additionally, cravings for nicotine weight gain, dizziness, coughing, constipation, bleeding gums or mouth ulcers, or a cold. Additionally, cravings for nicotine suffer Most side effects occur during the first three to four

weeks of treatment. The side effects depend on the amount you use and are due to incorrect chewing technique or the effects of nicotine. When you weeks of treatment. The side effects depend on the amount you use and are the result of incorrect chewing technique or the effects of nicotine. When you quickly, Nicorette may initially irritate the mouth or throat or cause hiccups or nausea. Allergic reactions are rare with nicotine use. The following side effects can occur very often (in

The following side effects may occur very frequently (in than 1 in 10 users): headache headache, coughing, hiccups, nausea, sore mouth of throat, throat irritation.

The following side effects may often occur (in less than 1 in 10 users): abdominal pain, diarrhea, dry mouth, indigestion, flatulence, excessive saliva, inflammation of the oral mucosa, vomiting, aburning sensation in the mouth, fatigue, hypersensitivity, altered taste perception, tingling. The gum can stick to dentures and, in rare cases, damage them.

The following side effects may sometimes occur (in less than 1 in 100 users): palpitations, increased heart rate, belching, tongue inflammation, blistering and peeling of the oral mucosa, reduced sensitivity in the mouth, general body weakness, unpleasant feeling and chest pain, uncomfortable feeling, jaw pain (stiff jaw), abnormal dreams, airway constriction, hoarseness, shortness of breath, nasal congestion, sore throat, sneezing, tight throat, sweating, itching, rash, rash with or without severe itching and formation of welts (hives or urticaria), flushing, increased blood pressure.

Swallowing disorders, a numb feeling in the mouth, and gagging may rarely occur (in less than 1 in 1,000 users) when using Nicorette.

The following side effect can very rarely occur (in less than 1 in 10,000 users): severe hypersensitivity reaction.

The frequency of the following side effects is not known: blurred vision, increased tear production, dry throat, gastrointestinal complaints, lip pain, stiff muscles, itchy edema of skin or mucous membranes, redness, seizures.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre (website: www.lareb.nl). By reporting side effects to reporting helps us to get more information about the safety of this medicine.

5. How do you store this medicine?

Store below 25°C.

Keep out of the sight and reach of children.

Do not use this medicine anymore after the expiry date. You can find it on the packaging after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or the toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. pharmacist what you should do with medicines you no longer use. If you dispose of medicines correctly, they are destroyed properly and do not end up in the environment.

6. Contents of the package and other information

What substances are in this medicine?

Nicorette Sugar-Free 2 mg gum

- The active substance in this medicine is nicotine. Each piece of gum contains nicotine resin, equivalent to 2 mg of nicotine.
- The other substances in this medicine are sodium bicarbonate (E500), anhydrous sodium carbonate (E500), gum base (contains BHT), sorbitol powder (E420i), sorbitol 70% (E420ii), flavorings, glycerol 85% (E422), and talc (E553b). Aroma pro fumendi (flavoring) contains traces of ethanol, cinnamal, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, linalool. Nicorette Sugar-Free 4 mg gum

The active substance in this medicine is nicotine. Each piece of gum contains nicotine resin, equivalent to 4 mg of nicotine.

- The other substances in this medicine are anhydrous sodium carbonate (E500), gum base (contains BHT), sorbitol powder (E420i), sorbitol 70% (E420ii), flavorings, glycerol 85% (E422), the colorant quinoline yellow (E104), and talc (E553b). Aroma pro fumendi (flavoring) contains traces of ethanol, cinnamal, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, linalool. Nicorette Sugar-Free Freshfruit 2 mg gum
- The active substance in this medicine is nicotine. Each piece of gum contains nicotine resin, equivalent to 2 mg of nicotine. 85% (E422), the colorant quinoline yellow (E104) and talc (E553b). Aroma pro fume Nicorette Sugar-Free Freshfruit 4 mg gum

Nicorette Sugar-Free Freshfruit 2 mg gum

- The active substance in this medicine is nicotine. Each gum contains nicotinesinate, corresponding to 2 mg nicotine.
- The other ingredients in this medicine are sodium bicarbonate (E500), anhydrous sodium carbonate (E500), gum base (contains BHT), xylitol (E967), peppermint oil, levomenthol, acesulfame potassium, light magnesium oxide (E530), talc (E553b) and nitrogen. Coating: xylitol (E967), tutti-frutti QL84441, acacia spray-dried, titanium dioxide, carnauba wax, hypromellose, sucralose, polysorbate 80 and purified water.

Nicorette Sugar-Free Freshfruit 4 mg gum

- The active substance in this medicine is nicotine. Each gum contains nicotine resinate, equivalent to 4 mg nicotine.
- The other substances in this medicine are anhydrous sodium carbonate (E500), gum base (contains BHT), xylitol (E967), peppermint oil, levomenthol, potassium acesulfame, colloidal magnesium oxide (E530), the coloring agent quinoline yellow (E104), talc (E553b), and nitrogen. Coating: xylitol (E967), tutti-frutti QL84441, acacia spray-dried, titanium dioxide, carnauba wax, the coloring agent quinoline yellow (E104) hypromellose, sucralose, polysorbate 80, and purified water.

(For additional information on some ingredients, see section 2)

What does Nicorette look like and what is in a package?

Nicorette Sugar-Free 2 mg is a square gum, beige in color.

Nicorette Sugar-Free 4 mg is a square gum, yellow in color.

Nicorette Sugar-Free Freshfruit 2 mg is a square gum, with coating, white in color.

Nicorette Sugar-Free Freshfruit 4 mg is a square gum, with coating, ivory in color.

Nicorette Sugar-Free 2 mg and 4 mg are available in boxes of 30 or 105 gums, in blister packaging (Al/PVC/PVDC).

Nicorette Sugar-Free Freshfruit 2 mg and 4 mg are available in boxes of 12, 15, 24, 30, 48, 90, 96, 105, 204 or 210 gums, in blister packaging (Al/PVC/PVDC).

It is possible that not all mentioned package sizes are marketed. marketed. Holder of the marketing authorization

Marketing authorization holder bring Kenvue Netherlands B.V.

Stadsplateau 27
3521 AZ Utrecht

Manufacturer

McNeil AB
Norrbroplatsen 2
251 09 Helsingborg
Sweden

Numbers of the marketing authorization trade bring

Nicorette Sugar-Free 2 mg gum: RVG 09155

Nicorette Sugar-Free 4 mg gum: RVG 14228

Nicorette Sugar-Free Freshfruit 2 mg gum: RVG 32548

Nicorette Sugar-Free Freshfruit 4 mg gum: RVG 32549

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