



Nicotinell

FRUIT-MINT NICOTINE

2 mg/4 mg Fruit – 2 mg/4 mg Mint Chewing Gum



Information for the patient

What is Nicotinell 2 mg chewing gum or 4 mg chewing gum and when is it used?

Nicotinell 2 mg or 4 mg chewing gum contains nicotine. It is recommended as an aid to help you stop smoking by providing you with a nicotine intake for a limited period of time after you have decided to give up smoking. The chances of not starting smoking again are better if you use nicotine replacement such as Nicotinell 2 mg or 4 mg chewing gum.

Nicotinell 2 mg or 4 mg chewing gum relieves the unpleasant effects of withdrawal and reduces the urge to smoke. While you are chewing Nicotinell 2 mg or 4 mg chewing gum, particularly during the first 30 minutes, the nicotine which it contains is gradually released and passes into your blood circulation via the buccal mucosa. You do not come into contact with any of the other harmful substances in tobacco, such as carbon monoxide, tar or stimulant gas. Nicotine reduces the symptoms of withdrawal which occur while you are giving up smoking, such as a pressing need for a cigarette, irritability, bad mood, anxiety, fear, hunger, putting on weight, difficulty in concentrating and sleep problems.

The quantities of nicotine absorbed with Nicotinell 2 mg or 4 mg chewing gum are generally lower than when you are smoking.

What do you have to take into account apart from the gum itself?

It might take you a few days to find the best way of using the product (chewing routine, local irritation due to the active ingredient, i.e. nicotine, see under "How to use...").

Nicotinell 2 mg or 4 mg chewing gum can only really help you if you are sufficiently motivated to give up smoking.

It is particularly helpful to combine Nicotinell 2 mg or 4 mg chewing gum with other forms of treatment such as smoking cessation programmes or individual counselling.

When should you not use Nicotinell 2 mg chewing gum or 4 mg chewing gum?

Nicotinell gum is contraindicated in non-smokers, children, and in principle in adolescents. The preparation should not be taken by adolescents except in exceptional circumstances (e.g. very strong dependency on smoking) and after they have seen a doctor or pharmacist.

Nicotinell 2 mg or 4 mg chewing gum should not be used by people with serious heart or circulation disorders (unstable angina, very recent myocardial infarction or cerebrovascular accident, or life-threatening cardiac arrhythmias), nor if the buccal or gastric mucosa are particularly sensitive to nicotine or if you are particularly sensitive to other ingredients in the product (see "What does Nicotinell chewing gum contain?").

What precautions should you take when using Nicotinell 2 mg chewing gum or 4 mg chewing gum?

The most important precaution is that you must stop smoking as soon as you start taking Nicotinell 2 mg or 4 mg chewing gum.

If you continue smoking while you are taking Nicotinell 2 mg or 4 mg chewing gum, you may experience side-effects caused by an overdose of nicotine.

If you suffer from any health disorders or if you have one of the following conditions, you should discuss the advantages and drawbacks of treatment with your doctor before starting: stable angina, previously had a myocardial infarction, serious cardiac arrhythmia, heart failure, circulation disorders in your arms or legs (e.g. arterial disease in the lower extremities in smokers), blood vessel disorders, recent cerebrovascular disease (within the last three months), diabetes, kidney or liver disease, hyperthyroidism, very high blood pressure and inflammation of the stomach lining or acute peptic ulcer.

If you are suffering from any of these disorders, you should not consider using Nicotinell 2 mg or 4 mg chewing gum unless it is impossible for you to give up smoking without taking medicines to help you.

You should see your doctor if you develop symptoms of circulation disorders, or if existing symptoms get worse (chest pain, irregular pulse, respiratory problems). Tobacco smoke contains substances such as tar, carbon monoxide and irritant gases which can cause or aggravate serious diseases such as bronchitis, lung cancer or heart attack, in addition to nicotine which contributes very little to causing these diseases. In contrast, nicotine is the ingredient which makes you dependent on smoking and which is responsible for the various withdrawal symptoms which appear when you give up.

Whether or not you use Nicotinell 2 mg or 4 mg chewing gum, reducing the amount you smoke can change your body's reaction to medicines that are taken at the same time. Ask your doctor if you need to change the dose of any of the medicines you are taking.

Please tell your doctor or pharmacist if

- you are suffering from any other disease,
- you have allergies,
- you are already taking other medicines (even as self-medication).

Can Nicotinell 2 mg chewing, or 4 mg chewing gum be used during pregnancy and breast-feeding?

Nicotine should not be taken in any form during pregnancy or breast-feeding; this also applies to Nicotinell 2 mg or 4 mg chewing gum. Discuss with your doctor how you are going to give up smoking during this time.

How should Nicotinell 2 mg chewing gum or 4 mg chewing gum be used?

Nicotinell 2 mg or 4 mg chewing gum should generally be used only by adults over 18 (see "When should Nicotinell 2 mg chewing gum or 4 mg chewing gum not be used?").

It is your personal motivation and your wish to persevere which will determine how successful you are in giving up smoking with the help of Nicotinell 2 mg or 4 mg chewing gum.

This is why it is important that you stop smoking completely as soon as you start treatment.

Nicotinell 2 mg chewing gum is particularly suitable for helping smokers give up when they smoke less than 20 cigarettes a day.

Nicotinell 4 mg chewing gum is suitable for helping heavy smokers give up (more than 20 cigarettes a day).

Giving up smoking with the help of Nicotinell 2 mg or 4 mg chewing gum makes it possible to adjust your nicotine intake to your individual requirements. Just chew one piece of Nicotinell 2 mg chewing gum or 4 mg chewing gum every time you feel the need to smoke. Usually 8–12 pieces of 2 mg or 4 mg chewing gum are sufficient, and in no circumstances should you take more than 15 pieces of 2 mg or 4 mg chewing gum a day.

It is important that you chew the gum correctly and use the right routine:

- Chew it slowly and evenly.
- If you feel a burning sensation or irritation in your mouth (or possibly a very strong taste), stop chewing for 1–2 minutes (see under "What side effects..."). This will stop the release of nicotine and the irritation should quickly disappear.
- Then start chewing again, still chewing slowly and evenly.
- It should take about 30 minutes to chew one piece of chewing gum.
- Avoid drinking just before and during chewing, so that you do not reduce the effect of the nicotine.

Reducing dependency to smoking should not take longer than three months. In principle, you should gradually reduce your nicotine intake at the latest two months after you start treatment; you could, for example, change from Nicotinell 4 mg chewing gum to Nicotinell 2 mg chewing gum, or gradually reduce the number of pieces of chewing gum used a day.

Please stick to the dose shown on the leaflet or prescribed by a doctor. If you think that the medicine is not sufficiently effective, or conversely, too strong, please see your doctor or pharmacist.

What side effects can Nicotinell chewing gum have?

The side-effects are the same as those from smoking too heavily. At the start of treatment, it is possible that chewing too quickly will cause local irritation in the mouth (a slight burning sensation), hiccupping or nausea caused by the active ingredient, nicotine. After a few days, you will generally have learnt the correct chewing routine (see under "How to use...") and have become used to the chewing gum.

Common side-effects: headache, nausea, gastrointestinal disorders, hiccupping, pain in the chewing muscles, irritation in the mouth and throat.

Less common side-effects: abnormal sensation on the skin, racing pulse and palpitations, redness of the skin and urticaria.

Cardiac arrhythmia has been reported in very rare cases. Some side-effects such as mouth ulcers, vertigo, headache and insomnia may also occur because you are giving up smoking, and as a result of withdrawal. It is possible that nicotine dependency will persist.

In children, particularly very young children, accidental consumption or overdose of Nicotinell 2 mg or 4 mg chewing gum can have serious consequences for their health. Overdose can also occur in adults if several pieces of chewing gum are chewed at the same time, or if they smoke at the same time. The signs of overdose are the same as those for acute nicotine poisoning, i.e. nausea, increased salivation, abdominal pain, diarrhoea, excessive sweating, headache, vertigo, hearing problems and severe weakness.

The intake of nicotine should be stopped immediately in this situation.

What else should be taken into account?

Nicotinell 2 mg chewing gum and 4 mg are sweetened with saccharin and are therefore suitable for diabetics.

They do not contain either lactose or galactose.

Keep Nicotinell 2 mg chewing gum and 4 mg chewing gum in a place to which children do not have easy access, and dispose of the chewing gum after use in such a way that children will not find it.

Medicines should be kept out of the reach of children. Protect from heat. Do not store above 25 °C. The product may be used up to the date -EXP- shown on the package.

If you need more information, ask your doctor or pharmacist, who have detailed information intended for health professionals.

What does Nicotinell chewing gum contain?

Nicotinell Fruit chewing gum 2 mg: 2 mg nicotine in the form of a resin complex, sorbitol (equivalent to 0.744 kcal), saccharin, antioxidant: butylated hydroxytoluene (E 321), flavours, other excipients.

Nicotinell Mint chewing gum 2 mg: 2 mg nicotine in the form of a resin complex, sorbitol (equivalent to 0.768 kcal), saccharin, antioxidant: butylated hydroxytoluene (E 321), flavours, other excipients.

Nicotinell Fruit chewing gum 4 mg: 4 mg nicotine in the form of a resin complex, sorbitol (equivalent to 0.652 kcal), saccharin, antioxidant: butylated hydroxytoluene (E 321), flavours, other excipients.

Nicotinell Mint chewing gum 4 mg: 4 mg nicotine in the form of a resin complex, sorbitol (equivalent to 0.672 kcal), saccharin, antioxidant: butylated hydroxytoluene (E 321), flavours, other excipients.

What packs are marketed

Nicotinell 2 mg chewing gum: boxes containing 12 pieces.
Nicotinell 4 mg chewing gum: boxes containing 12 pieces.

Novartis Consumer Health SA Nyon Switzerland

Information updated

December 1999.

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your 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 the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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