

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nicotinell Fruit 4 mg medicated chewing-gum

Nicotinell Mint 4 mg medicated chewing gum

Nicotine

Read all of this 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 to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What Nicotinell chewing-gum is and what it is used for

Nicotinell medicated chewing-gum is a nicotine replacement therapy (NRT) which is used to help you to stop smoking.

It is used to relieve and /or prevent withdrawal symptoms and reduce the cravings you get when you try and stop smoking or when cutting down on the number of cigarettes you smoke.

It is available in two strengths (2 mg and 4 mg).

The chewing-gum contains nicotine, which is one of the substances in tobacco. When chewed, nicotine is released slowly and absorbed through the lining of the mouth. Nicotinell chewing-gum does not contain the other harmful substances found in tobacco smoke such as tar and carbon monoxide.

Ideally you should always aim to stop smoking completely, but Nicotinell gums can be used in a number of ways to help you:

- cut down the amount you smoke – perhaps before you go on to stop completely.
- to reduce the number of cigarettes you smoke - which can increase the chances that you will move on to quit completely

In addition, they may be used when you:

- do not wish to smoke. For example in confined spaces (in the car or house) or where others could be harmed by tobacco smoke e.g. children
- are unable to smoke
- develop cravings once you have stopped smoking
- experience withdrawal effects that frequently occur when giving up smoking such as feeling ill or irritable

- have a desire to smoke by providing some of the nicotine previously inhaled from cigarettes and therefore helps your willpower to resist cigarettes

Nicotinell 4 mg gum is for smokers smoking more than 30 cigarettes per day. It can also be used by smokers smoking between 20 and 30 cigarettes per day.

You might feel a sudden craving to smoke long after you have given up smoking and stopped using Nicotinell gums. Remember you can use any nicotine replacement therapy again if this should happen.

To help quit smoking you should also try to use a behavioural support programme to increase your chances of success.

If you need advice before starting to use Nicotinell gum, talk to your doctor, nurse, pharmacist or trained counsellor.

2. What you need to know before you take Nicotinell chewing-gum

Do NOT take Nicotinell chewing-gum if you are

- allergic (hypersensitive) to nicotine or any of the other ingredients of the chewing-gum (listed in section 6).
- a non-smoker or occasional smoker.

Warnings and precautions

Talk to your doctor, pharmacist before taking the chewing-gum if you:

- are in hospital for heart disease, (including heart attack, worsening chest pain, disorders of the heart rate and/or rhythm, angina, including Prinzmetal's angina)
- have uncontrolled high blood pressure
- have recently had a stroke
- suffer from liver or kidney problems
- have or had a stomach ulcer or oesophagitis
- have persistent indigestion
- have a severe sore throat or inflammation of the mouth
- are diabetic (see "Other medicines and Nicotinell Chewing-gums")
- have an overactive thyroid gland
- have a tumour of the adrenal glands (phaeochromocytoma)
- have ever experienced seizures
- are fructose intolerant
- are on a low-sodium diet
- are taking any other medicines (see "Other medicines and Nicotinell Chewing-gums").
- are pregnant or breast-feeding (see Pregnancy/Breast-feeding sections).

People having problems with the jawbone and some denture wearers may experience difficulty in chewing the gum. If you do, it is recommended that you use a different form of nicotine replacement therapy, such as a patch or lozenge. Ask your doctor or pharmacist for advice.

Using nicotine replacement therapy is better than continuing to smoke.

Children and adolescents

If you are under 18 years old, ask a healthcare professional before use. Adolescents should not quit with a combination NRT Regimen.

Children under 12 years should not use the gum unless advised by a doctor.

Other medicines and Nicotinell Chewing-gums

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

The effect of some medicines can be altered when you stop smoking and may require adjustment of the dose.

- If you are already taking **regular medication** you should tell your doctor or pharmacist.
- **Diabetics** should monitor their blood sugar levels more often than usual when taking chewing gum because your insulin/medication requirements may alter.

Taking Nicotinell chewing-gum with food and drink

Coffee, juices, acidic and fizzy drinks may reduce the absorption of nicotine and should not be taken for 15 minutes before chewing the gum.

Pregnancy

Smoking during pregnancy is associated with risks such as poor growth of the baby before birth, premature birth or still birth. Stopping smoking is the single most effective way to improve both your health and that of your baby. The earlier smoking stops, the better.

Ideally, stopping smoking during pregnancy should be done without nicotine replacement therapy.

However, if you have tried and this has not worked, nicotine replacement therapy may be used when the risk to the developing baby is less than that expected from continued smoking.

- The decision to use nicotine replacement therapy should be made as early on in the pregnancy as possible
- Aim on discontinuing use after 2-3 months
- Patches may be preferred if you have nausea or sickness

Breast-feeding

If you are breast-feeding, you should first stop smoking without using nicotine replacement therapy. Stopping completely is by far the best option. However, if you have tried and this has not worked, nicotine replacement therapy should only be used upon advice by a healthcare professional because nicotine can pass into breast milk.

- It is better to use nicotine replacement therapy products that can be taken intermittently (not patches).
- Try to breast-feed at a time just before you take the product to ensure that the baby gets the smallest amount of nicotine possible.

If you need to use nicotine replacement therapy to help you give up smoking, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the second-hand smoke they would otherwise be breathing in.

Fertility

Smoking increases the risk for infertility in women and men.

Driving and using machines

The chewing gum is unlikely to affect your ability to drive or operate machinery. However, smoking cessation can cause behavioural changes.

Nicotinell contains sorbitol, butylhydroxytoluene and sodium

Because Nicotinell Mint and Fruit contain sorbitol, which is a source of fructose: if you have been told by your doctor that you have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, contact your doctor before taking this medicine.

The gum base contains butylhydroxytoluene (E321) which may cause local irritation to mucous membranes.

Each piece of Nicotinell Mint and Fruit 4 mg contains sweeteners, including sorbitol (E420) 0.2 g, a source of 0.04 g fructose. Calorific value 1.0 kcal/piece.

Nicotinell Mint and Fruit 2 mg contains less than 1 mmol sodium (23 mg) per chewing gum, that is to say essentially 'sodium-free'.

For other ingredients see Section 6.

3. How to take Nicotinell chewing-gum

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

The recommended dose for adults over 18 years and older people is:

Chew one piece of gum when you feel the urge to smoke. It is important to chew the gum correctly, not like ordinary chewing-gum.

Follow the instructions below and do NOT swallow the gum:

Chewing technique:

1. Chew one piece of gum slowly until the taste becomes strong. Do not use more than 1 gum per hour.
2. Rest between your gum and cheek.
3. Chew again when taste has faded.
4. Repeat this chewing routine for about 30 minutes, to get a gradual release of nicotine.

Most people use 8 - 12 pieces of 4 mg gum a day.

Do NOT use more than 1 piece of gum at a time or more than 15 pieces of 4 mg gum a day.

Do not drink certain drinks 15 minutes before chewing the gum (see Section 2).

The gum can stick to but very rarely damage dentures or other dental work. However, you may prefer to use a patch or lozenge.

After 3 months, you should try to gradually reduce the number of pieces of gum chewed each day.

You should stop using the gum when you are only taking 1-2 pieces of gum per day. Nicotine gum should not be used for more than 12 months unless the potential benefit outweighs the potential risk to the smokers.

If you take more Nicotinell chewing-gums than you should

If you accidentally take too many, or if a child has eaten any, contact your doctor or nearest hospital casualty department immediately, take the pack or leaflet with you if possible.

Nicotine ingestion by a child may result in severe poisoning.

The general symptoms of nicotine overdose include:

- weakness, excess sweating, pale skin, increased production of saliva, throat burn, feeling sick, headache, vomiting, diarrhoea, stomach pains, disturbed hearing and vision, confusion, tremor, disturbance in heartbeat, shortness of breath and circulatory problems

If you forget to use Nicotinell chewing-gums

Do not take a double dose to make up for a forgotten dose.

Only chew the gum when you need to. Do NOT use more than 1 piece of gum at a time or more than 24 pieces of 4 mg gum a day.

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

4. Possible side effects

Like all medicines, Nicotinell chewing-gums can cause side effects, although not everybody gets them.

STOP using the gum and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty breathing or swallowing, swelling of the mouth, face, lips, tongue or throat.
- severe itching of the skin, with a red rash or raised lumps.

Some effects you may notice in the first few days are dizziness, headache and sleep disturbances. These may be withdrawal symptoms in connection with smoking cessation and may be caused by insufficient administration of nicotine.

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

- nausea

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

- dizziness and headache.
- stomach trouble (such as flatulence, vomiting, pain) increased saliva production, diarrhoea, dry mouth, constipation, irritation of the mouth and throat
- indigestion, heartburn or hiccups may also occur, especially as a result of intense chewing. Check that you are following the correct chewing technique if you experience these effects.
- insomnia
- cough and sore throat

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

- itching of raised bumps of the skin (urticaria).

Not known (*frequency cannot be estimated from the available data*)

- tremor
- heartbeat irregularities
- a fast and irregular heartbeat (Atrial fibrillation)
- breathing difficulty
- difficulty swallowing or belching
- weakness, fatigue or flu-like symptoms
- seizures

Mouth ulcers may be related to quitting smoking and not to your treatment.

Nicotinell chewing-gum can stick to and very rarely damage dentures or other dental work.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. or search for the MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicotinell chewing-gum

- Keep out of the sight and reach of children.
- Do not use Nicotinell gums after the expiry date which is stated on the blister pack and carton after “EXP”. The expiry date refers to the last day of that month.
- Do not store above 25°C.

To dispose of used gum, wrap in paper before putting into a waste bin. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Nicotinell chewing-gum contains

- The **active substance** is nicotine.
- Each piece of gum contains 4 mg of nicotine in a resin complex (as 20 mg nicotine-polacrilin).
- The **other ingredients** are
- gum base, calcium carbonate (E170), sorbitol (E420), sodium carbonate anhydrous, sodium hydrogen carbonate (E500), glycerol (E422), levomenthol, butylhydroxytoluene (E321)), saccharin, saccharin sodium (E954), acesulfame potassium (E950), xylitol (E967), mannitol (E421), gelatin, titanium dioxide (E171), carnauba wax (E903) and talc (E553b), water.
- Fruit 4mg Gum contains fruit flavouring
- Mint 4mg Gum contains peppermint oil and eucalyptus oil.

Nicotinell gum is sugar-free.

What Nicotinell chewing-gum looks like and contents of the pack

Each piece of chewing-gum is off-white in colour and rectangular in shape.

The Fruit and Mint 4 mg Gums are packed in blisters inside boxes containing 12, 24, 36, 72, 96, 120 or 204 pieces of gum. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

Fertin Pharma A/S, Dandyvej 19, DK-7100 Vejle

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