PACKAGE LEAFLET: INFORMATION FOR THE USER

Nicotinell Cool Mint 2 mg medicated chewing-gum

Nicotine

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

This medicine is available without prescription. However, you still need to use Nicotinell Cool Mint 2 mg medicated chewing-gum carefully to get the best results from it.

Always take this medicine exactly as described in this leaflet or as your pharmacist has 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 or pharmacist. This includes any possible side effects not listed in this leaflet. **See section 4.**
- You must contact a doctor if you still need to use Nicotinell after 9 months.

What is in this leaflet:

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

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

Nicotinell belongs to a group of medicines which are used to help you to stop smoking. Nicotinell contains the active substance nicotine.

When chewed, nicotine is released slowly and absorbed through the lining of the mouth.

This medicinal product is used to relieve the nicotine withdrawal symptoms in nicotine dependency, as an aid to smoking cessation.

Patient counselling and support normally improve the success rate.

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

Do not take Nicotinell

- If you are allergic (hypersensitive) to nicotine or any of the other ingredients of this medicine (listed in section 6)
- If you are a non-smoker.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nicotinell if you have:

- any heart problems, you should consult a healthcare professional before using any nicotine replacement therapy product. While using a nicotine replacement therapy product, if you experience an increase in heart problems, the use of the product should be reduced or discontinued.
- recently had a heart attack or stroke or suffer from severe heart rhythm problems or chest pain, you should try to quit smoking without using any nicotine replacement therapy products unless your doctor tells you to use them.
- heart failure, angina, Prinzmetal's angina or high blood pressure (uncontrolled hypertension),
- problems with your circulation,
- diabetes , you should monitor your blood sugar levels more often than usual when you start using nicotine gum. Your insulin or medicine requirements may change.
- overactive thyroid glands (hyperthyroidism),
- overactive adrenal glands (pheochromocytoma),
- suffer from impaired kidney or liver disease,
- stomach or duodenal ulcers or an inflamed oesophagus or gullet (the passage between the mouth and stomach) because nicotine replacement therapy can make your symptoms worse.
- fructose intolerance.
- ever experienced seizures

Keep all medicines out of the sight and reach of children.

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

Children and adolescents

Even small quantities of nicotine are dangerous in children and may result in severe symptoms or death. If poisoning is suspected in a child, consult a healthcare professional immediately. It is therefore essential that you keep Nicotinell out of the sight and reach of children at all times.

Other medicines and Nicotinell

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines. Stopping smoking may alter the effect of other medicines you may be taking. If you have any questions or concerns about this, talk to a healthcare professional.

No information is available on interactions between Nicotinell and other medicines. However, apart from nicotine, other substances in cigarettes may have an effect on certain medicine.

Stopping smoking can affect the action of certain medicines e.g.:
- theophyllin (a medicine used for the treatment of bronchial asthma)
- tacrine (medicine used to treat Alzheimer's disease)
- olanzapine and clozapine (for the treatment of schizophrenia)
- Insulin dose (medicine used for the treatment of diabetes) may need to be adjusted

Nicotinell with food and drink

Coffee, acidic drinks (e.g. fruit juice) and soft drinks may decrease the absorption of nicotine and should be avoided for 15 minutes before chewing Nicotinell because they may affect the absorption of nicotine.

Pregnancy,breast-feeding and fertility

Pregnancy

If you are pregnant, you should stop smoking without using nicotine replacement therapy. However, if you have tried and this has not worked, nicotine replacement therapy should only be used upon advice by a healthcare professional to help you stop smoking.

Breast-feeding

If you are breastfeeding, nicotine replacement therapy should only be used upon advice by a healthcare professional because nicotine can pass into breast milk.

Fertility

Smoking increases the risk for infertility in women and men.

Driving and using machines

There is no evidence of risk associated with driving or operating machinery if Nicotinell is taken according to the recommended dose but remember that smoking cessation can cause behavioural changes.

Nicotinell contains sorbitol, butylhydroxytoluene and sodium

Because Nicotinell Mint contains 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. If you cannot tolerate sorbitol do not use this product.

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

Each piece of Nicotinell Mint 2 mg contains sweeteners, including sorbitol (E420) 0.2 g, a source of 0.04 g fructose. Calorific value 1.0 kcal/piece.

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

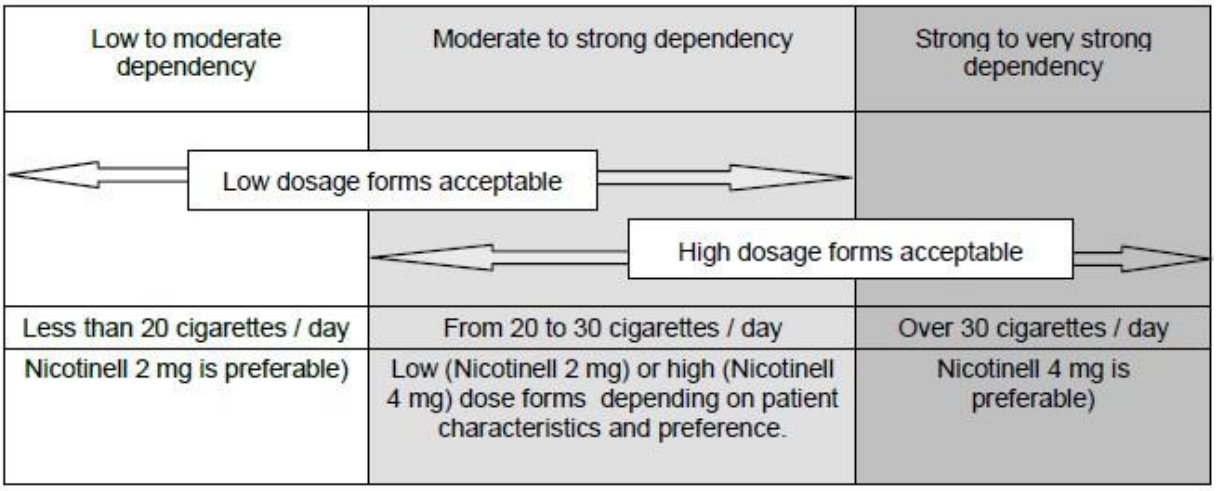
3. How to use Nicotinell medicated chewing-gum

Always take Nicotinell exactly as described in this package leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

To improve your chances of giving up smoking you should stop smoking completely when you start to use Nicotinell and for the whole treatment duration.
Nicotinell is available in two strengths: 2 and 4 mg. The appropriate dose will depend on your previous smoking habits. You should use Nicotinell 4 mg if:

- you are a smoker with a strong or very strong nicotine dependency,
- you have previously failed to stop smoking with Nicotinell 2 mg,
- your withdrawal symptoms remain so strong as to threaten relapse.

Otherwise Nicotinell 2 mg should be used.
Select your optimal dosage from the following table:



If an adverse event occurs with the use of the high dose (Nicotinell 4 mg), use of the low dose (Nicotinell 2 mg) should be considered.

Method of administration

Begin using this product on your quit day. In order to successfully quit smoking with this treatment, you should completely stop smoking.
Chew 1 piece of gum when urge to smoke occurs. Do not use more than 1 gum at a time. Do not use more than 1 gum per hour.

1. Chew one piece of Nicotinell slowly until the taste becomes strong. Do not eat or drink while you have a gum in your mouth.
2. Allow Nicotinell to rest between your gum and cheek.
3. Chew again when taste has faded.
4. Repeat this routine for about 30 minutes, to get a gradual release of nicotine.

Do not swallow.

Dosage for adults over 18 years:

Chew one piece of Nicotinell when you feel the urge to smoke. In general one piece should be chewed every one or two hours. Normally 8-12 pieces per day are sufficient. If you still experience an urge to smoke, you can chew additional pieces of Nicotinell. Do not exceed 24 pieces a day of Nicotinell 2 mg.

The treatment duration is individual. Normally, treatment should continue for at least 3 months. After 3 months, you should gradually reduce the number of pieces of Nicotinell chewed each day. Treatment should be stopped when you have reduced your use of Nicotinell to 1-2 pieces per day. It is generally not recommended to use Nicotinell for longer than 6 months. However, some ex-smokers may need treatment with Nicotinell for longer to avoid returning to smoking.

If you are still using Nicotinell after 9 months, you should speak to your doctor or pharmacist.

Counselling may improve your chances of giving up smoking.

Use in children and adolescents

Nicotinell should **not** be used by people under 18 years of age without recommendation from a doctor.

If you take more Nicotinell than you should

Chewing too many Nicotinell pieces can result in the same symptoms as smoking too much. . If you use too many nicotine gums you may start to feel sick, dizzy and unwell. Stop using the gums and consult a healthcare professional immediately. The general symptoms of nicotine overdose include weakness, pale skin, increased sweating, involuntary muscle contractions, increased production of saliva, dizziness, throat burn, nausea, vomiting, diarrhoea, pain in the abdomen, disturbance of hearing and vision, headache, fast or other disturbance in heartbeat (tachycardia), shortness of breath, confusion, prostration, circulatory problems, coma and terminal convulsions.

With very large overdoses, exhaustion, seizures, low blood pressure leading to circulatory collapse or respiratory failure may occur.

You should consult your doctor or pharmacist if you experience any problems.

If poisoning is suspected in a child, a doctor must be consulted immediately. Even small quantities of nicotine are dangerous and potentially life-threatening in children and may result in severe symptoms or death.

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

If you forget to use Nicotinell
Do not take a double dose to make up for a forgotten dose.

If you stop taking Nicotinell
If you have any further questions on the use of this medicine, ask your doctor or pharmacist

4. Possible side effects

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

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.

They are group based on the likelihood with which they can occur:

Very common side effects (affects 1 in every 10 people)
- feeling sick (nausea)

Common side effects (may affect 1 to 10 people in every 100 people)
- the gums may cause your mouth or tongue to be slightly sore or irritated.
- sore or swollen throat
- being sick
- stomach discomfort
- diarrhoea
- indigestion/heartburn
- flatulence
- hiccups
- increased saliva production
- constipation
- difficulty in swallowing
- dizziness and headache
- vomiting
- insomina
- cough
- dryness of the mouth

- and jaw muscle ache may also occur, especially as a result of intense chewing. Slower chewing will usually overcome these problems

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

- feeling your heartbeat (palpitations).
- itching of raised bumps of the skin (urticaria).

Rare side effects (may affect up to 1 in every 1000 people)

- a fast and irregular heartbeat (atrial fibrillation)
- shortness of breath
- severe allergic reaction symptoms of which include sudden wheeziness or tightness of chest, rash and feeling faint.
- disturbances in heart beat rhythm and allergic reactions. These reactions may in very few cases be serious and include swelling of the skin, swelling of the face and mouth, low blood pressure and difficulty in breathing.

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

Nicotinell 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme www.mhra.gov.uk/yellowcard. . or search for 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 medicated chewing-gum

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

Do not use Nicotinell after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

Used Nicotinell should be disposed of with care.

Do not throw away 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 contains

The **active substance** is nicotine.

Each piece of Nicotinell medicated chewing-gum contains 2 mg of nicotine (as 10 mg nicotine-polacrilin)

The **other ingredients** are
gum base (containing butylhydroxytoluene (E321)), calcium carbonate, sorbitol (E420), sodium carbonate anhydrous, sodium hydrogen carbonate, polacrilin, glycerol (E422), purified water, levomenthol, peppermint oil, eucalyptus oil, saccharin, sodium saccharin, acesulfame potassium, xylitol (E967), mannitol (E421), gelatin, titanium dioxide (E171), carnauba wax and talc. See section 2 "Nicotinell contains sorbitol, butylhydroxytoluene and sodium"

What Nicotinell looks like and contents of the pack

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

Nicotinell medicated chewing-gum is available in two strengths (2 and 4 mg) and four flavours (Fruit, Mint**,** Liquorice and Classic). This package leaflet deals with Nicotinell Mint 2 mg medicated chewing-gums.

The blisters are packed in boxes containing 2, 12, 24, 36, 48, 60, 72, 96 or 204 pieces of medicated chewing-gum. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Dr. Reddy's Laboratories (UK) Ltd.
410 Cambridge Science Park, Milton Road
Cambridge, CB4 0PE
United Kingdom

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

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