

PACKAGE LEAFLET: INFORMATION FOR THE USER



Read all of this leaflet carefully because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Ask your doctor, nurse or pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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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 available in two strengths (2 mg and 4 mg) and five flavours (Fruit, Mint, Icemint, Liquorice and Classic). This leaflet is for Nicotinell Fruit and Mint, 4 mg medicated chewing-gums.

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.

Nicotinell 4mg gum can be used to help you:

- stop smoking completely
- cut down the amount you smoke - perhaps before you go on to stop completely.

In addition, they may be used when you:

- do not wish to smoke. For example in confined spaces (in the car: in the house) or where others (such as children) could be harmed by tobacco smoke
- are unable to smoke
- develop cravings once you have stopped smoking.

Reducing the number of cigarettes smoked can increase the chances that you will move on to quit completely.

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, and by those who have previously failed to stop smoking with the aid of nicotine replacement therapy.

If you smoke less than 20 cigarettes per day then you should use Nicotinell 2 mg medicated chewing-gum.

Smokers of more than 20 cigarettes per day, who are reducing their smoking prior to a quit attempt, should use the lower strength Nicotinell 2mg gums once they have successfully reduced the number of cigarettes smoked per day.

Nicotinell 2mg and 4mg gums can also be used to relieve breakthrough cravings of smokers attempting to quit by following a patch programme.

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.

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

To help quit smoking you should also try to use a behavioural support programme to increase your chances of success. Talk to your doctor, nurse, pharmacist or a trained counsellor about this.

2 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
- a non-smoker or occasional smoker

- under 12 years of age, except on the advice of a doctor.

Take special care with Nicotinell chewing-gum
Please speak with your doctor, nurse or pharmacist **before** taking the chewing-gum if you:

- have heart disease, (e.g. heart attack, worsening chest pain, disorders of the heart rate and/or rhythm)
- have uncontrolled high blood pressure
- have recently had a stroke
- have serious liver or kidney disease
- have or had a stomach ulcer
- have persistent indigestion
- have a severe sore throat or inflammation of the mouth
- are diabetic (see next section)
- have an overactive thyroid gland
- have a tumour of the adrenal glands (pheochromocytoma)
- are fructose intolerant
- are on a low-sodium diet
- are taking any other medicines (see next section)
- 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of some medicines can be altered when you stop smoking.

- If you are already taking **regular medication** you should tell your doctor, nurse 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 is not possible, nicotine replacement therapy may be used because 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 with the aim of discontinuing use after 2-3 months.

Ask your doctor for advice before taking any medicine.

Breast-feeding

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.

Driving and using machines

The chewing gum is unlikely to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Nicotinell Medicated chewing gum

These chewing-gums contain some ingredients of which you may need to be aware of:

- **sorbitol:** if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Each piece of fruit and mint flavour gum contains 0.2g, a source of 0.04 g fructose. Each piece of Ice mint flavour gum contains 0.1g, a source of 0.02 g fructose.
- **sodium:** Each piece of fruit and mint flavour gum contains 11.5 mg per piece. Each piece of Ice mint flavour gum contains 11.45 mg per piece. To be taken into consideration by those on a controlled sodium diet
- **butylhydroxytoluene (E321):** an ingredient of the gum base which may cause local irritation to the lining of the mouth.

For other ingredients see Section 6.

3 How to take Nicotinell chewing-gum

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.
2. Rest between your gum and cheek.
3. Chew again when taste has faded.
4. Repeat this chewing routine for about 30 minutes.

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.

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

The gum can stick to and very rarely damage dentures or other dental work. You may prefer to use a patch or lozenge.

After 3 months, you should 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.

For the relief of breakthrough cravings:

If you are attempting to quit smoking using a patch programme, you can use these gums to relieve any breakthrough cravings you may experience. Chew one piece of gum if you feel the need to smoke.

Counselling may improve your chances of giving up smoking.

Children and adolescents (12 -18 years) should only use the gum for 12 weeks. If longer is required then talk to your doctor, nurse or pharmacist.

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

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, sweating, increased production of saliva, throat burn, headache, sickness, diarrhoea stomach pains, disturbed hearing and vision, disturbance in heartbeat, shortness of breath and circulatory problems

If you forget to use Nicotinell chewing-gums

Only chew the gum when you need to. Do NOT use more than 1 piece of gum at a time or more than 15 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 side 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.

Common side effects (occur in 1 to 10 users in 100)

- dizziness and headache.
- Hiccups, stomach trouble such as nausea, flatulence, vomiting, heartburn, increased saliva production, irritation of the mouth and throat and jaw muscle ache may also occur, especially as a result of intense chewing. Check that you are following the correct chewing technique if you experience these effects.

Uncommon side effects (occur in 1 to 10 users in 1,000)

- palpitations.
- red skin rash (erythema) and itching of raised bumps of the skin (urticaria).

Rare side effects (occur in 1 to 10 users in 10,000)

- disturbances in heart beat rhythm and allergic reactions.

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

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

5 How to store Nicotinell chewing-gum

Keep out of the reach and sight of children.

Do not use Nicotinell gums after the expiry date which is stated on the blister pack and box 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. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Nicotinell chewing-gum contains

The **active substance** is nicotine.

Each piece of Nicotinell medicated chewing-gum contains 4 mg of nicotine in a resin complex (as 20 mg nicotine polacrillin).

The **other ingredients of Nicotinell Fruit and Mint flavoured gums** 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), talc (E553b), water.

(see also Section 2 for further ingredient information).

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 and 204 pieces of gum. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Novartis Consumer Health, Camberley, GU15 3YL, UK.

Marketing Authorisation Holder

FAMAR S.A., 48th km Athens-Lamia, 19011, Avlona, Greece.

Help/Advice

You can also find additional information and support @ www.smokefree.nhs.uk or by calling the NHS helpline on 0800 0224322.

This leaflet was last approved June 2013.