

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.
- You must contact a doctor if your symptoms worsen or do not improve after 9 months.
- 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.

In this leaflet:

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

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

Nicotinell medicated chewing-gum is a type of nicotine replacement therapy which is used to help you to stop smoking. It is available in two strengths (2 mg and 4 mg) and four flavours (Fruit, Mint, Licorice and Classic). This leaflet is for Nicotinell Fruit and Mint, 2 mg medicated chewing-gums. The chewing-gum contains nicotine, which is one of the substances contained 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.

This medicinal product is used to:

- relieve some of the unpleasant nicotine withdrawal symptoms that frequently occur when giving up smoking such as feeling ill or irritable.
- reduce your desire to smoke by providing some of the nicotine previously inhaled from cigarettes and therefore helps your willpower to resist cigarettes.

Nicotinell 2 mg gum is for smokers smoking less than 20 cigarettes per day. It can also be used by smokers smoking between 20 and 30 cigarettes per day.

If you smoke more than 30 cigarettes per day, you should use Nicotinell 4 mg medicated chewing-gum.

If you need advice before starting to use Nicotinell gum, talk to your doctor, nurse, pharmacist or trained counsellor. A support programme will increase your chances of quitting smoking.

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

You should stop smoking completely during treatment with Nicotinell gum. Continuing to smoke while using the gums they may result in increased adverse effects being experienced including

adverse cardiovascular effects. Please speak with your doctor, nurse or pharmacist **before** taking the chewing-gum if you:

- have heart disease, (e.g. heart attack, disorders of the heart rate and/or rhythm)
- have or 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)
- have fructose intolerance
- are on a low-sodium diet
- are taking any other medicines (see next section)
- are pregnant or breast-feeding (see Pregnancy/Breast-feeding sections).

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 contains 0.2g, a source of 0.04 g fructose.
- **sodium:** 11.5 mg per piece. To be taken into consideration by those on a controlled sodium diet

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 2 mg gum a day.

Do NOT use more than 1 piece of gum at a time or more than 25 pieces of 2 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 must 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. **It is generally not recommended to use Nicotinell chewing-gum for longer than 6 months.** However, some ex-smokers may need longer to avoid returning to smoking. If you are still using the gum after 9 months, you should talk to your doctor or pharmacist. 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.

The general symptoms of nicotine overdose include:

- headache, sickness, diarrhoea and stomach pains

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 2 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.

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.

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. 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.

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.

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 2 mg of nicotine in a resin complex (as 20 mg nicotine polacriliin).

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), talc (E553b), water. (see also Section 2 for further ingredient information)

Flavours:

- Fruit 2 mg Gum contains fruit flavouring
- Mint 2 mg 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 2 mg Gums are packed in blisters inside boxes containing 12, 24, 96, 120 or 204 pieces of gum. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novartis Consumer Health, Horsham, RH12 5AB, UK.

This leaflet was last approved in **mmmm yyyy**.

GB 900054/PIL USER TEST

NOVARTIS

<p>Northampton Itarus House, Tenter Road, Moulton Park, Northampton NN3 6PZ Need help? Contact us: +44 (0)1604 468100 mail@itarus.com www.itarus.com</p>	<p>Customer: Novartis Customer Ref: -- ARA No: 1556 Job Description: Nicotinell National Fruit And Mint Gum 2mg UK Leaflet - User Testing Job No: 123130 File No: 49963 Printer: -- Packer: -- File Name: 123130v1_12.ai Rev. Date: 14/12/2009 Rev. Time: 10:30 Barcode: -- Size/BWR: 000%/000 Profile ref: Supplied Operator: 29 Output Queue: PDF Spec: - No of Cols: 1 Dispro: N/A DGC: N/A</p>	<p>PROOF CHECK & COMMENTS When you have checked this proof and made your comments, please sign and date the appropriate boxes</p> <p>Signature: _____</p> <p>Print Name: _____ Date: _____</p>	<p>QUALITY CONTROL</p> <p>Operator <input type="text"/></p> <p>Project Organiser <input type="text"/></p> <p>Version 1</p>
<p>Wedges: 2% 40% 80% 25% 50% 75% 75° 150#</p>			