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**PACKAGE LEAFLET: INFORMATION FOR THE USER****Nicotinell Fruit 2 mg medicated chewing-gum****Nicotinell Fruit 4 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 Fruit 2 mg medicated chewing-gum **Nicotinell Fruit 4 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.

*To be completed nationally for ES:*

- 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 6 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 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**

### **Do not take Nicotinell**

- If you are allergic to nicotine or any of the active 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 liverdisease.
- 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 or have recently taken any other 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 medicines.

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 medicated chewing-gum 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 and breast-feeding**

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

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

Each piece of Nicotinell Fruit 4 mg contains sweeteners, including sorbitol (E420) 0.2 g, a source of 0.04 g fructose. Calorific value 0.9 kcal/piece.

Nicotinell Fruit 4 mg contains less than 1 mmol sodium (23 mg) per chewing gum, that is to say essentially 'sodium free'.

### 3. How to take Nicotinell

Always take this medicine 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:

Low to moderate dependency	Moderate to strong dependency	Strong to very strong dependency
← Low dosage forms acceptable →		← High dosage forms acceptable →
Less than 20 cigarettes / day	From 20 to 30 cigarettes / day	Over 30 cigarettes / day
Nicotinell 2 mg is preferable)	Low (Nicotinell 2 mg) or high (Nicotinell 4 mg) dose forms depending on patient characteristics and preference.	Nicotinell 4 mg is preferable)

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.

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

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 15 pieces per day of Nicotinell 4mg.

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.

*To be completed nationally for ES:*

If you are still using Nicotinell after 6 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 possibly life-threatening in children and may result in severe symptoms or death.

If you have any further questions on the use of this medicine, 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 (may affect 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
- diarrhea
- indigestion/heartburn
- flatulence

- hiccups
- increased saliva production
- constipation
- difficulty in swallowing
- dizziness and headache
- vomiting
- insomnia
- 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)**

- fast or irregular heartbeat.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V\*. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Nicotinell**

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).

Each piece of Nicotinell medicated chewing-gum contains 4 mg of nicotine (as 20 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, tutti flavour, 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 medicated chewing-gum 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 Fruit 2 mg 4 mg medicated chewing-gums.

The blisters are packed in boxes containing 2, 12, 24, 36, 48, 60, 72, 96, 120 or 204 pieces of medicated chewing-gum. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<b>AT</b>	Nicotinell Fruit 2 mg - wirkstoffhaltige Kaugummi zur Raucherentwöhnung
<b>BE</b>	Nicotinell Fruit, 2 mg, kauwgom
<b>DK</b>	Nicotinell Fruit, medicinsk tyggegummi
<b>EE</b>	Nicotinell Fruit
<b>EL</b>	Nicotinell Fruit



<b>ES</b>	Nicotinell fruit 2 mg chicle medicamentoso
<b>FI</b>	Nicotinell Fruit 2 mg lääkepurukumi
<b>FR</b>	NICOTINELL FRUIT 2 mg SANS SUCRE, gomme à mâcher médicamenteuse
<b>HU</b>	Nicotinell Fruit 2 mg gyógyszeres ráógumi
<b>IE</b>	Nicotinell Fruit 2mg Medicated Chewing Gum.
<b>LT</b>	Nicotinell Fruit 2 mg vaistinė kramtomoji guma
<b>LU</b>	Nicotinell Fruit, 2 mg, gomme à mâcher médicamenteuse
<b>LV</b>	Nicotinell Fruit 2 mg ārstnieciskā košļājamā gumija
<b>NL</b>	Nicotinell Fruit, 2 mg, kauwgom
<b>NO</b>	Nicotinell medisinsk tyggegummi med fruktsmak
<b>PT</b>	Nicotinell Fruit 2 mg
<b>SE</b>	Nicotinell Fruit 2 mg medicinskt tuggummi
<b>UK</b>	Nicotinell Fruit 2mg Medicated Chewing Gum.

<b>AT</b>	Nicotinell Fruit 4 mg - wirkstoffhaltige Kaugummi zur Raucherentwöhnung
<b>BE</b>	Nicotinell Fruit, 4 mg, kauwgom
<b>DK</b>	Nicotinell Fruit, medicinsk tyggegummi
<b>EE</b>	Nicotinell Fruit
<b>EL</b>	Nicotinell Fruit
<b>ES</b>	Nicotinell fruit 4 mg chicle medicamentoso
<b>FI</b>	Nicotinell Fruit 4 mg lääkepurukumi
<b>FR</b>	NICOTINELL FRUIT 4 mg SANS SUCRE, gomme à mâcher médicamenteuse
<b>IE</b>	Nicotinell Fruit 4mg Medicated Chewing Gum.

<b>LT</b>	Nicotinell Fruit 4 mg vaistinė kramtomoji guma
<b>LU</b>	Nicotinell Fruit, 4 mg, gomme à mâcher médicamenteuse
<b>LV</b>	Nicotinell Fruit 4 mg ārstnieciskā košļājamā gumija
<b>NL</b>	Nicotinell Fruit, 4 mg, kauwgom
<b>NO</b>	Nicotinell medisinsk tyggegummi med fruktsmak
<b>PT</b>	Nicotinell Fruit 4 mg
<b>SE</b>	Nicotinell Fruit 4 mg medicinskt tuggummi.
<b>UK</b>	Nicotinell Fruit 4mg Medicated Chewing Gum.

This leaflet was last revised in July 2021.