

## **Package leaflet: Information for the user**

### **Nicotinell Classic 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 Classic 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.
- You must contact a doctor if you still need to use Nicotinell after 9 months.
- 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.

In this leaflet:

1. What Nicotinell is and what it is used for
2. What you need to know before you take Nicotinell
3. How to take Nicotinell
4. Possible side effects
5. How to store Nicotinell
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 nicotine, which is one of the substances contained in tobacco.

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 (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:

- heart disease, e.g. heart attack, heart failure, angina, Prinzmetal's angina or abnormalities in heart beat rhythm,
- had a "stroke" (cerebrovascular accident),
- high blood pressure (uncontrolled hypertension),
- problems with your circulation,
- diabetes (monitor your blood sugar levels more often when starting to use Nicotinell as you may find your insulin or medication requirements alter)
- overactive thyroid glands (hyperthyroidism),
- overactive adrenal glands (pheochromocytoma),
- kidney or liver disease,
- oesophagitis, inflammation in the mouth or throat, gastritis or peptic ulcer,
- fructose intolerance.

Even small quantities of nicotine are dangerous in children and may result in severe symptoms or death. It is therefore essential that you keep Nicotinell out of reach and sight of children at all times

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.

## **Other medicines and Nicotinell**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you stop smoking and if you are using other medicines, your doctor may want to adjust the dose.

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.

## **Pregnancy and breast-feeding**

It is very important to stop smoking during pregnancy because it can result in poor growth of your baby. It can also lead to premature births and even stillbirths. Ideally you should try to give up smoking without the use of medicines. If you cannot manage this, Nicotinell may be recommended to help as the risk to the developing baby is less than that expected from continued smoking. Nicotine in any form may cause harm to your unborn baby. Nicotinell should only be used after consulting the

healthcare professional who is managing your pregnancy, or a doctor that is specialised in helping people quit smoking.

Nicotinell like smoking itself should be avoided during breast-feeding as nicotine may be found in breast milk. If your doctor has recommended that you should take this medicinal product, the medicated chewing-gum should be taken just after breast-feeding and not during the two hours before breast-feeding.

### 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 Classic contains sorbitol and maltitol liquid: if you have been told by your doctor that you have an intolerance to some sugars, 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 Classic 4 mg contains sweeteners, including sorbitol (E420) 0.2 g and maltitol liquid (E965) 0.03 g, a source of 0.04 g fructose. Calorific value 1.1 kcal/piece.

Nicotinell Classic 4 mg contains 11.52 mg of sodium per piece. To be taken into consideration by patients on a controlled sodium diet.

## 3. How to use Nicotinell

Always use 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:

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.

Instructions for use:

1. Chew one piece of Nicotinell slowly until the taste becomes strong.
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 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.

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. The general symptoms of nicotine overdose include weakness, sweating, 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 heart beat (tachycardia and cardiac arrhythmia), shortness of breath, prostration, circulatory problems, coma and terminal convulsions.

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 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.

#### **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.

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

- 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.  
Slower chewing will usually overcome these problems.

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

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

**Rare side effects** (may affect up to 1 in 1,000 people)

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). 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 any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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 4 mg of nicotine (as 20 mg nicotine-polacrilin).

The other ingredients are

- gum base (containing butylhydroxytoluene (E321)), calcium carbonate, sorbitol (E420), maltitol liquid (E965), sodium carbonate anhydrous, sodium hydrogen carbonate, polacrilin, glycerol (E422), purified water, levomenthol, tutti flavour, 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 Classic 4 mg medicated chewing-gums.

Nicotinell medicated chewing-gum contains reduced amount of flavouring and is specifically recommended if you prefer the classic nicotine taste.

The blisters are packed in boxes containing 2, 12, 24, 36, 48, 60, 72, 84, 96, 120 or 204 pieces of medicated chewing-gum. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Novartis Consumer Health UK Limited  
Park View, Riverside Way  
Watchmoor Park, Camberley, Surrey GU15 3YL

### **Manufacturer**

FAMAR S.A., 48<sup>th</sup> km National Road Athens-Lamia, 19011, Avlonas, Attiki, Greece

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

<b>BE</b>	Nicotinell Classic, 4 mg, kauwgom
<b>DK</b>	Nicotinell Classic
<b>FI</b>	Nicotinell 4 mg lääkepurukumi
<b>IE</b>	Nicotinell Classic 4mg Medicated Chewing Gum.
<b>IS</b>	Nicotinell Classic 4 mg lyfjatyggigúmmí
<b>LU</b>	Nicotinell Classic, 4 mg, gomme à mâcher médicamenteuse
<b>NL</b>	Nicotinell Classic, 4 mg, kauwgom
<b>NO</b>	Nicotinell medisinsk tyggegummi med nøytral smak
<b>PT</b>	Nicotinell Classic 4mg

<b>SE</b>	Nicotinell 4 mg, medicinskt tuggummi
<b>UK</b>	Nicotinell Classic 4mg Medicated Chewing Gum

This leaflet was last approved in May 2015