

## Package leaflet: Information for the user

### Nicotinell Spearmint 2 mg medicated chewing-gum Nicotinell Spearmint 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.**

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 doctor or 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.**

#### **What is in this leaflet:**

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

#### **1. What Nicotinell Spearmint is and what is used for**

Nicotinell Spearmint belongs to a group of medicines which are used to help you to stop smoking.

Nicotinell Spearmint chewing-gum 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 nicotine craving and withdrawal symptoms in nicotine dependency. It thereby - counteracts the relapse in smoking in smokers who are motivated to stop or - facilitate smoking reduction in smokers who cannot or are reluctant to stop.

Patient counselling and support normally improve the success rate.

Nicotinell Spearmint is indicated for smokers aged 18 years and above.

#### **2. What you need to know before you take Nicotinell Spearmint**



##### **Do not take Nicotinell Spearmint**

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



##### **Warnings and precautions**

Talk to your doctor before using Nicotinell Spearmint 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
- 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 lozenge. Your insulin or medicine requirements may change.
- overactive thyroid glands,
- overactive adrenal glands (pheochromocytoma),
- suffer from impaired kidney and/or liver function
- fructose intolerance
- oesophagitis, inflammation in the mouth or throat, gastritis or peptic ulcer
- a history of epilepsy (fits).

In these conditions it is not sure that it is suitable for you to use Nicotinell Spearmint.

People having problems with the joint of the jawbone and 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. Chewing the Nicotinell Spearmint gum may loosen fillings or dental implants.

Do not smoke while taking Nicotinell Spearmint, since you may obtain a high concentration of nicotine that will cause you to feel unwell.



#### **Children and adolescents**

Nicotinell should not be used by adolescents 12-17 years of age without recommendation from a doctor. The correct dose for adults could seriously poison or be fatal to small children. It is therefore essential that you keep Nicotinell Spearmint out of the sight and reach of children at all times. Nicotinell Spearmint are not to be used in children under 12 years old.



#### **Other medicines and Nicotinell Spearmint**

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 Spearmint chewing-gum and other medicines. However, the action of some drugs may be affected if you stop smoking. This is particularly important if you use drugs containing

- theophylline (a medicine used for the treatment of bronchial asthma) ,
- tacrine (a medicine used to treat Alzheimer's disease),
- olanzapine and clozapine (for the treatment of schizophrenia).



#### **Nicotinell Spearmint with food and drink**



Coffee, acidic and soft drinks may decrease the absorption of nicotine and should be avoided for 15 minutes before chewing a Nicotinell Spearmint chewing-gum. Do not eat or drink while you have a gum in your mouth.



## **Fertility, pregnancy and breast-feeding**

### Pregnancy

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. It is best if you can give up smoking without the use of medicines containing nicotine. If you cannot manage this, Nicotinell Spearmint should only be used after consulting a healthcare professional.

### Breast-feeding

Nicotinell Spearmint should be avoided during breast-feeding as nicotine found in breast milk and may affect your child. If a healthcare professional has recommended you to use Nicotinell Spearmint during breast-feeding, the gum should be chewed just after breast-feeding and not during the two hours before breast-feeding.

### Fertility

Smoking increases the risk of infertility in women and men. The effects of nicotine on fertility is unknown.



## **Driving and using machines**

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



## **Nicotinell Spearmint contains sorbitol, butylhydroxytoluene and sodium**

Because Nicotinell Spearmint chewing-gum 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 Nicotinell Spearmint chewing-gum.

Each piece of chewing-gum contains 0.1 g sorbitol, a source of 0.02 g fructose. Calorific value 1.0 kcal/piece of chewing-gum (Nicotinell Spearmint 2 mg) and 0.9 kcal/piece (Nicotinell Spearmint 4 mg) respectively.

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

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

### **3. How to use Nicotinell Spearmint**

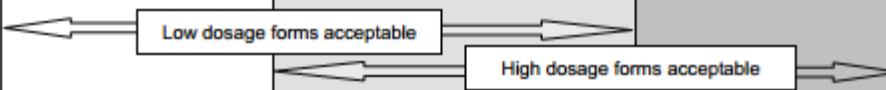
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The appropriate strength will depend on your nicotine dependence. You should use the 4 mg Nicotinell Spearmint chewing-gum if

- you are a smoker with a strong nicotine dependency,
- you have previously failed to stop smoking with the 2 mg chewing-gum.

Otherwise 2 mg Nicotinell Spearmint chewing-gum should be used.

Select your optimal strength from the following table:

| Low to moderate dependency   | Moderate to strong dependency   | Strong to very strong dependency |
|--|---|----------------------------------|
|  |   |                                  |
| 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 (4 mg), use of the low dose (2 mg) should be considered.

It is important to chew the chewing-gum in a correct way to avoid discomfort (e.g. hiccups and heart burn).



#### **Instructions for use:**

Do not swallow the chewing-gum.

1. Chew one piece of chewing-gum slowly until the taste becomes strong.
2. Allow the chewing-gum to rest between your gum and cheek.
3. Chew again when taste has faded.
4. Repeat this routine for about 30 minutes.

Avoid drinking coffee, acidic and soft drinks for 15 minutes before chewing a Nicotinell Spearmint chewing gum because they may decrease the absorption of nicotine. Do not eat or drink while you have a gum in your mouth.

#### **Dosage for adults over 18 years:**

Chew one piece of gum when you feel the urge to smoke.

At the beginning of the treatment, in general, one piece of chewing-gum should be chewed every one or two hours. Normally 8-12 pieces of chewing-gum per day are sufficient, irrespective of strength. Do not exceed 24 pieces a day of 2 mg chewing-gum or 15 pieces per day of 4 mg chewing-gum. Do not use more than 1 gum per hour.

#### *Smoking cessation:*

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 gum chewed each day. Treatment should be stopped when you have reduced your use of the gum to 1-2 chewing-gums per day. It is generally not recommended to use Nicotinell Spearmint chewing-gum for longer than 1 year.

However, some ex-smokers may need treatment with the chewing-gum for longer to avoid returning to smoking.

Counselling may improve your chances of giving up smoking.

*Smoking reduction:*

Nicotinell Spearmint is used between periods of smoking in order to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in the number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought. A quit attempt should be made as soon as you feel ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

Counselling may improve your chances of giving up smoking.



**If you take more Nicotinell Spearmint than you should**

Chewing too many chewing-gum pieces can result in the same symptoms as smoking too much. The symptoms of nicotine overdose include: weakness, pale skin, 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 heartbeat, shortness of breath, tremor and confusion.

With large overdoses, these symptoms may be followed by exhaustion, low blood pressure, circulatory collapse, coma, difficulty breathing and seizures.

Stop using the gums and contact a doctor or hospital immediately for assessment of risk and advice, if you have taken more of the drug than you should, or if a child has taken the drug by mistake.

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 forget to use Nicotinell Spearmint**

Do not take a double dose to make up for a forgotten dose.

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. Other possible withdrawal symptoms in connection with smoking cessation may be insomnia, cough, weakness, tiredness, feeling unwell and flu-like symptoms.

Stop taking Nicotinell Spearmint and contact immediately a doctor if you get any of the following symptoms of a serious allergic reaction (angioedema or anaphylactic reaction)

- swelling of face, tongue or throat; difficulty swallowing; hives and breathing difficulties.

These side effects are rare.

**Other side effects that may occur:**

**Very common** (may affect more than 1 in 10 people)

- feeling sick (nausea)

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

- inflammation of the mouth mucous, oral discomfort
- sore throat
- vomiting
- stomach discomfort, stomach pain
- diarrhoea
- indigestion/heartburn
- flatulence
- hiccups
- constipation
- dizziness and headache
- insomnia
- cough
- dryness of the mouth, mouth, throat and jaw muscle ache may also occur

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

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

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

- disturbances in heart beat rhythm
- hypersensitivity reaction

**Not known**

- increased secretion of saliva
- difficulty in swallowing
- tremor
- ulcerative stomatitis.

Mouth ulcers may be related to quitting smoking and not to your treatment. The gum can stick to and 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 HPRRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Nicotinell Spearmint**

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

Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Spearmint contains

Nicotinell Spearmint medicated chewing-gum is available in two strengths.

The **active substance** is nicotine.

Each piece of Nicotinell Spearmint chewing-gum contains 2 mg or 4 mg nicotine (as 10 mg or 20 mg nicotine polacrillin (1:4)).

### The other ingredients are:

Gum base (containing butylhydroxytoluene (E321)), xylitol, calcium carbonate (E170), sorbitol (E420), mannitol (E421), sodium carbonate anhydrous, sodium hydrogen carbonate, natural mint flavouring, Novamint spearmint, polacrillin, glycerol, levomenthol, sucralose, gelatine, titanium dioxide (E171), acesulfame potassium (E950), carnauba wax and talc.

Nicotinell Spearmint medicated chewing gum is sugar free.

### What Nicotinell Spearmint looks like and contents of the pack

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

The chewing-gums are packed in blisters containing 12 chewing-gums. The blisters are packed in boxes containing 12, 24, 48, 84, 96 or 204 pieces of chewing-gum.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

### Manufacturer

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

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

|           |  |
|-----------|--|
| <b>DK</b> | Nicotinell Spearmint medicinsk tyggegummi 2 mg and 4 mg  |
| <b>FI</b> | Nicotinell Spearmint 2 mg and 4 mg lääkepurukumi         |
| <b>IE</b> | Nicotinell Spearmint 2mg and 4 mg Medicated Chewing Gum  |
| <b>IS</b> | Nicotinell Spearmint 2 mg and 4 mg lyfjatyggigúmmí       |
| <b>NO</b> | Nicotinell 2 mg and 4 mg medisinsk tyggegummi Spearmint  |
| <b>SE</b> | Nicotinell Spearmint 2 mg and 4 mg                       |
| <b>UK</b> | Nicotinell Spearmint 2mg and 4 mg Medicated Chewing Gum. |

**This leaflet was last revised in September 2020.**