Package leaflet: Information for the user

Nicotinell Mint 1 mg Compressed Lozenge
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 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 Lozenge after 9 months.

What is in this leaflet:

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

1. What Nicotinell Mint Lozenge is and what it is used for

Nicotinell Mint Lozenge belongs to a group of medicines which are used to help you stop smoking. Nicotinell Mint Lozenge contains the active substance nicotine.

When sucked, nicotine is released slowly and absorbed through the lining of the mouth.

This medicinal product is used to help people stop smoking. The nicotine in Nicotinell Mint relieves nicotine withdrawal symptoms and cravings when you stop smoking or temporarily reduce smoking in order to facilitate smoking cessation. By relieving the withdrawal symptoms and cravings Nicotinell Mint counteracts a smoking relapse in smokers who are motivated to stop smoking.

Patient counselling and support normally improve the success rate.

Nicotinell Mint Lozenge is indicated for smokers aged 18 years and above.

2. What you need to know before you take Nicotinell Mint Lozenge

Do not take Nicotinell Mint Lozenge

- If you are allergic 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 Mint Lozenge if you have:
- any heart problems such as recently had a heart attack, suffer from heart rhythm problems, heart failure or chest pain (angina, including Prinzmetal's angina). While using this medicine, if you experience an increase in heart problems, the use of this medicine should be reduced or discontinued.
- had a "stroke" (cerebrovascular accident)
- high blood pressure.
- 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 (hyperthyroidism).
- overactive adrenal glands (pheochromocytoma)
- suffer from kidney or liver disease.
- oesophagitis, inflammation in the mouth or throat, gastritis or peptic ulcer.
- a history of epilepsy (fits).

Children and adolescents

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

Other medicines and Nicotinell Mint Lozenges

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Mint Lozenge 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.:

- theophylline (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 Mint Lozenge with food and drink

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

Pregnancy, breast-feeding and fertility

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 should only be used after consulting a healthcare professional.

Breast-feeding
Nicotinell Mint should be avoided during breast-feeding as nicotine is found in breast milk and may affect your child. If a healthcare professional has recommended you to use Nicotinell Mint during breast-feeding, the lozenge should be sucked 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 the lozenge is taken according to the recommended dose but remember that smoking cessation can cause behavioural changes.

Nicotinell Mint Lozenges contain aspartame, maltitol and sodium

This medicine contains 10 mg aspartame in each lozenge. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Because Nicotinell Mint 1 mg Lozenge contains maltitol (E965), a source of fructose:
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- patients may experience a mild laxative effect.

Calorific value 2.3 kcal/g maltitol. Nicotinell Mint Lozenge ingredients are suitable for diabetics.

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

3. How to take Nicotinell Mint Lozenge

Always take Nicotinell Mint Lozenge 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.

Nicotinell Mint Lozenge is available in two strengths: 1 mg and 2 mg.

Nicotinell Mint 1 mg Lozenge can be used alone *(a)* or in combination with Nicotinell Patches *(b)*.

Adults over 18 years
***(a)* Treatment with Nicotinell Mint Lozenges only**

Nicotinell Mint 1 mg Lozenge is recommended in low to moderate nicotine dependent smokers. It is not recommended for smokers with a strong or very strong nicotine dependency.

Select your optimal strength 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
Treatment with Nicotinell Mint Lozenge only	1 mg lozenge is preferable	Low (1 mg lozenge) or high (2 mg lozenge) dose forms depending on patient characteristics and preference	2 mg lozenge is preferable

If an adverse event occurs with the use of the high dose (2 mg lozenge), use of the low dose (1 mg lozenge) should be considered.

Dosage for adults over 18 years:
Suck one lozenge when you feel the urge to smoke. In general one lozenge should be taken every one or two hours. Normally 8-12 lozenges per day are sufficient. If you still experience an urge to smoke, you can suck additional lozenges. Do not exceed 24 lozenges per day of the 1 mg strength (applies for both smoking cessation and smoking reduction). Do not use more than 1 lozenge per hour.

Nicotinell Lozenge should primarily be used for smoking cessation.

Smoking cessation:
To improve your chances of giving up smoking you should stop smoking completely when you start to use the lozenges and for the whole treatment period.

The treatment duration is individual. Normally, treatment should continue for at least 3 months. After 3 months, you should gradually reduce the number of lozenges used each day. Treatment should be stopped when you have reduced your use of the lozenge to 1-2 lozenges per day. It is generally not recommended to use Nicotinell Mint Lozenge for longer than 6 months. However, some ex-smokers may need treatment with the lozenge for longer to avoid returning to smoking.

If you are still using the lozenge after 9 months, you should speak to your doctor or pharmacist.

Counselling may improve your chances of giving up smoking.

Smoking reduction:

Nicotinell Mint Lozenge should be used between periods of smoking in order to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. The number of cigarettes should be gradually replaced by Nicotinell Mint Lozenge. If, after 6 weeks, you have not succeeded in reducing the number of cigarettes per day to at least half of your consumption you should seek professional help. You should try to stop smoking as soon as you feel ready, but not later than 4 months after you started using Nicotinell Mint Lozenges. After that the number of lozenges should be gradually reduced, for example by quitting one lozenge every 2-5 days.

If you do not succeed in making a serious attempt to stop smoking within 6 months you should seek professional help. Regular use of Nicotinell Mint Lozenge beyond 6 months is generally not recommended. Some ex-smokers may need treatment with the lozenges for longer to avoid returning to smoking.

Counselling may improve your chances of giving up smoking.

Instructions for use:

Do not swallow the lozenge.
1. Suck a lozenge until the taste becomes strong.
2. Allow the lozenge to rest between your gum and cheek.
3. Suck again when the taste has faded.
4. Repeat this routine until the lozenge dissolves completely (about 30 minutes).

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

***(b)* Treatment with Nicotinell Mint 1 mg Lozenge in combination with Nicotinell Transdermal Patch**

Smoking cessation:
If you have failed treatment with only Nicotinell Lozenge you can use Nicotinell Patches together with Nicotinell 1 mg Lozenge.

NOTE: Read the package leaflet of Nicotinell Transdermal Patch prior to use.

To improve your chances of giving up smoking you should stop smoking completely when you start to use the lozenges in combination with Nicotinell Patches and for the whole treatment period.

The use of Nicotinell Patches together with Nicotinell 1 mg Lozenge is recommended for smokers with moderate to very strong dependency, i.e. over 20 cigarettes per day. It is strongly recommended that the combination therapy is carried out with the advice and support from a healthcare professional.

The combination therapy should only be used in smoking cessation.

Initial combination therapy:
Begin the treatment with one patch 21 mg/24 hours in combination with Nicotinell 1 mg Lozenge. Use at least 4 lozenges (1 mg) per day. In most cases, 5-6 lozenges are enough. Do not use more than 15 lozenges a day. In normal cases, the treatment may last for 6-12 weeks. Thereafter, you should reduce the nicotine dose gradually.

Apply the patch on a clean, dry, hairless, intact area of skin on the trunk, arms or hips and press it against the skin with your hand for 10- 20 seconds.

To minimize the risk of local irritation, the placement of Nicotinell Patches should alternate between different application sites.

Wash your hands thoroughly after application of transdermal patches to avoid irritation of the eyes with nicotine from the fingers.

Reduction of nicotine dose after the initial 6-12 weeks:
This can be done in two ways.
Alternative 1:
Use patches of a lower strength, i.e. 14 mg/24 hours patches for 3-6 weeks followed by 7 mg/24 hours for another 3-6 weeks together with the initial dose of Nicotinell 1 mg Lozenge. Thereafter, reduce the number of lozenges gradually. It is generally not recommended to use Nicotinell Mint Lozenge for longer than 6 months. However, some ex-smokers may need treatment for longer to avoid returning to smoking but it should not be more than 9 months.
Alternative 2:
Discontinue the use of the patch and reduce the number of 1 mg lozenges gradually. It is generally not recommended to use Nicotinell Mint Lozenge for longer than 6 months. However, some ex-smokers may need treatment for longer to avoid returning to smoking but it should not be more than 9 months.

Recommended dosage:

Period	**Patches**	**Lozenge 1 mg**
Initial treatment (followed by alternative 1 or 2 below)		
First 6-12 weeks	1 patch 21 mg/24 hours	When necessary, 5-6 lozenges per day is recommended
Reduction of nicotine dose – alternative 1		
Next 3-6 weeks	1 patch 14 mg/24 hours	Continue to use lozenges, when necessary
Following 3-6 weeks	1 patch 7 mg/24 hours	Continue to use lozenges, when necessary
Up to 9 months in total	-	Reduce the number of lozenges gradually
Reduction of nicotine dose – alternative 2		
Up to 9 months in total	-	Continue to reduce the number of lozenges gradually

If you are still using the lozenge and patches after 9 months, you should speak to your doctor or pharmacist.

If you take more Nicotinell Mint Lozenges than you should

Sucking too many lozenges 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 in breathing and seizures.

Stop taking the lozenges and contact a doctor 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 take Nicotinell Mint Lozenge

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 Mint and contact a doctor immediately 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
- 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 mucus, oral discomfort
- sore throat
- vomiting
- stomach discomfort, stomach pain
- diarrhoea
- indigestion/heartburn (slower sucking will usually overcome these problems)
- flatulence
- hiccups
- constipation
- dizziness and headache
- insomnia
- cough
- dryness of the mouth

Uncommon (may affect up to 1 in 100 people)
- palpitations

Rare (may affect up to 1 in 1000 people)
- disturbance in heart beat rhythm
- allergic reactions

Not known (cannot be estimated from the available data)
- hives (urticaria)
- ulcerative stomatitis
- tremor
- shortness of breath
- difficulty swallowing
- belching
- increased secretion of saliva
- weakness
- tiredness
- feeling unwell
- flu-like symptoms
- fast and irregular heartbeat (Atrial fibrillation)

Mouth ulcers may occur when trying to quit smoking, but the relationship to the nicotine treatment is not clear.

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. Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicotinell Mint Lozenge

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, blister and tube after "EXP". The expiry date refers to the last date of that month.

Do not store above 25°C. Store in the original package.

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 Mint Lozenge contains

The **active substance** is nicotine.
Each piece of Nicotinell Mint Lozenge contains 1 mg of nicotine (as 3.072 mg nicotine bitartrate dihydrate).

- The **other ingredients** are maltitol (E965), sodium carbonate anhydrous, sodium hydrogen carbonate, polyacrylate, xanthan gum, colloidal anhydrous silica, levomenthol, peppermint oil, aspartame (E951), magnesium stearate.

What Nicotinell Mint Lozenge looks like and contents of the pack

Nicotinell Mint Lozenge is a white, mint flavoured, round biconvex compressed lozenge.

Nicotinell Mint Lozenge is available in two strengths (1 mg and 2 mg). This package leaflet deals with Nicotinell Mint 1 mg Lozenges.

The blisters are packed in boxes containing 96 lozenges.

Parallel Product Authorisation holder
IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by
HALEON GERMANY GMBH, Barthstraße 4, 80339 München, Germany.

Repackaged by
Cast Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK(NI).

This medicine is authorised in the Member States of the European Economic Area under the following names

Austria	Nicotinell Mint 1 mg Lutschtabletten
Denmark	Nicotinell Mint 1 mg Sugetablet
Finland	Nicotinell Mint 1 mg Imeskelytabletti
France	Nicotinell Menthe 1 mg, comprimé à sucer
Germany	Nicotinell Lutschtabletten 1 mg Mint
Ireland	Nicotinell Mint 1 mg compressed Lozenge
Luxembourg	Nicotinell Mint 1 mg, comprimé à sucer
Netherlands	Nicotinell Mint 1 mg Zuigtablet
Portugal	Nicotinell Mint 1 mg Pastilhas
Spain	Nicotinell Mint 1 mg comprimidos para chupar
Sweden	Nicotinell Mint 1 mg sugtablett
United Kingdom (Northern Ireland)	Nicotinell Mint 1 mg Lozenge

For further information please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie.

Nicotinell is a registered trademark of Northstar Switzerland SARL.

This leaflet was last revised in June 2026.