

Information on how to use



Nicotinell Mint 1mg lozenges

Please read this leaflet carefully before taking Nicotinell Lozenge. This leaflet provides a summary of information on the lozenge. If you have any questions, ask your doctor or pharmacist.

What is in your lozenge?

Nicotinell Lozenge belongs to a group of medicines which are used to help you stop smoking. The lozenges are available in packs of 12, 36 or 96. Not all presentations may be available locally. Each lozenge contains nicotine 1mg in the form of nicotine bitartrate. Other ingredients are maltitol, sodium carbonate, sodium bicarbonate, polyacrylate dispersion, xanthan gum, colloidal anhydrous silica, levomenthol, peppermint oil, aspartame, magnesium stearate. The lozenge is sugar free.

What you need to know about Nicotinell Lozenge

Nicotinell Lozenge contains nicotine. When you suck the lozenge, the nicotine is slowly released and absorbed through the lining of the mouth. The lozenge can alleviate some of the unpleasant withdrawal effects that frequently occur when giving up smoking, such as cravings and irritability. The lozenge can reduce your desire to smoke and help improve your willpower to resist smoking by providing some of the nicotine previously inhaled. Nicotinell Lozenge is best suited for those with low nicotine dependency. It is not recommended for those who have found other forms of nicotine replacement therapy unsatisfactory. The nicotine dependence makes it difficult to stop smoking. The craving for cigarettes can continue for some time after you have ceased smoking. You still need to use your willpower to resist the urge to smoke. Advice and support will improve your success.

Before using Nicotinell Lozenge

Contains aspartame, a source of phenylalanine. This may be harmful to people with an inherited metabolic disease called phenylketonuria. Contains maltitol. If you cannot tolerate maltitol, do not use this product. **Contains 9.8mg sodium per lozenge.** Not to be taken by non-smokers.

Do not use if you are allergic to nicotine or any of the other ingredients in the lozenge.

Consult your doctor before using Nicotinell Lozenge:

- If you have diabetes you should monitor your blood sugar levels more often than usual when you start using nicotine lozenge. Your insulin or medication requirements may change.
- If you had a recent heart attack, stroke or suffer from severe heart rhythm problems or chest pain, you should try to quit smoking without using any NRT products unless your doctor tells you to use them.
- If you have any heart problems, you should consult a healthcare professional before using any NRT product. While using an NRT product, if you

experience an increase in heart problems, the use of the product should be reduced or discontinued.

- If you suffer from kidney or liver disease
- If you have 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.
- If you have ever experienced seizures.
- **If you have an overactive thyroid gland**
- **If you have high blood pressure, angina or circulatory problems**
- **If you have a tumour of the adrenal gland (pheochromocytoma)**
- **If you have inflammation of the mouth or sore throat**

If you are under 18 years of age, ask a doctor before use.

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.

If you are breastfeeding, nicotine replacement therapy should only be used upon advice by a healthcare professional because nicotine can pass into breastmilk.

The effect of some medicines can be altered when you stop smoking. If you are already taking regular medication, you should tell your doctor or pharmacist.

How to use Nicotinell Lozenge

Begin using this product on your quit day. In order to successfully quit smoking with this treatment, you should completely stop smoking.

Use 1 lozenge when urge to smoke occurs; do not use more than 1 lozenge at a time. Do not use more than 1 lozenge per hour. Do not chew or swallow the lozenge. Do not eat or drink while you have a lozenge in your mouth. Avoid drinking acidic beverages such as coffee or soda for 15 minutes prior to sucking the lozenge because they may affect the absorption of nicotine.

When starting treatment, 1 lozenge may be sucked every 1-2 hours. Most people suck 8-12 lozenges per day.

Do not use more than **20 pieces** of 1mg lozenges per day.

If you smoke 20 or more cigarettes per day you should use the 2mg lozenge; otherwise the 1mg dose lozenge is recommended.

If an adverse event occurs with the use of the higher dose form of Nicotinell lozenge, it is recommended to use the lower dose form or consult your healthcare professional.

Duration of use

For best results, you are recommended to complete the 12-week treatment course. If you are still using the lozenge after 12 weeks, you should gradually reduce the nicotine dose and discontinue when the dose has been reduced to 1-2 pieces/day. If you are still using nicotine lozenge after 6 months, talk to your healthcare professional for advice.

Nicotinell sucking technique

One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other and repeated until the lozenge is completely dissolved (approximately 20 - 30 minutes for lozenges). **Sucking the lozenge slowly can help to overcome some of the side effects.** The lozenge must not be chewed or swallowed. Users should not eat or drink while a lozenge is in the mouth. In the event of accidental overdose, or if a child has eaten any, contact your doctor or nearest casualty

department and show them the pack or leaflet. Nicotinell Lozenge is not suitable for children, who may develop signs of nicotine overdose. The general symptoms of nicotine overdose include headache, sickness, stomach pains and diarrhoea. If you use too many nicotine lozenges, you may start to feel sick, dizzy and unwell. Stop using the lozenge and seek medical advice immediately.

Even small quantities of nicotine are dangerous in children and may result in severe symptoms of poisoning which may prove fatal. If poisoning is suspected in a child, consult a healthcare professional immediately.

Pale skin, increased sweating, involuntary muscle contractions, sensory disturbances, and confusion may be experienced.

With very large overdoses, exhaustion, seizures, low blood pressure leading to circulatory collapse or respiratory failure may occur.

After taking Nicotinell Lozenge

Some of the side effects you may encounter are (from most likely to least likely):

- Feeling sick (nausea)
- Dryness of the mouth
- Cough
- Insomnia
- Vomiting
- Dizziness and headache
- Difficulty in swallowing
- Constipation
- Increased saliva production
- Hiccups
- Flatulence
- Indigestion/heartburn
- Diarrhea
- Stomach discomfort
- Being sick
- Sore or swollen throat
- The lozenges may cause your mouth or tongue to be slightly sore or irritated
- Shortness of breath
- Fast or irregular heartbeat
- Severe allergic reaction symptoms of which include sudden wheeziness or tightness of chest, rash and feeling faint

Tell your doctor or pharmacist if you notice any other effect that you think might be caused by using the lozenge.

Further remarks

Do not use Nicotinell Lozenge after the expiry date shown on the label or on the lozenge blister. Keep all medicines out of the reach and sight of children. Do not store above 25 °C. Keep the lozenge in the blister strip.

Date of information

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