

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

**Nicotinell Lozenges 1 mg**

**Nicotinell Lozenges 2 mg**

Nicotinell Lozenges 1 mg – Each lozenge contains: 1 mg nicotine

Nicotinell Lozenges 2 mg – Each lozenge contains: 2 mg nicotine

Inactive ingredients and allergens in the preparation – please see section 6.

**Read the entire leaflet carefully before using the medicine.**

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

The medicine is intended for adults over 18 years old.

Take the preparation according to the instructions in the dosage section of this leaflet in the “How should you use the medicine?” section. Consult the pharmacist if you need more information.

Contact the doctor, if you still need to use the medicine after nine months of use.

**1. What is the medicine intended for?**

To help stop smoking and relieve nicotine withdrawal symptoms. **For adults above 18 years of age.**

For smokers who are currently unable or unwilling to stop smoking at once, the lozenges can also be used as part of a program to reduce smoking before stopping completely.

Nicotinell Lozenges contain nicotine, which is one of the ingredients of tobacco.

When sucked, the nicotine is released slowly and absorbed through the oral mucosa.

**Therapeutic class:** Medicines used in conditions of nicotine dependence.

**2. Before using the medicine**

**Do not use this medicine if:**

- |  |
|--|
| <ul style="list-style-type: none"><li>• You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains (See section 6).</li><li>• You are a non-smoker.</li></ul> |
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## **Special warnings regarding the use of the medicine**

Before treatment with Nicotinell Lozenges 1 mg and 2 mg inform the doctor if:

- You suffer from a heart disease, such as: you have recently had a heart attack, heart failure, angina pectoris, variant angina (Prinzmetal's angina) or heart arrhythmias. If you experience worsening of your heart disease while taking this medicine, you will need to reduce or discontinue the use of this medicine.
- You have previously had a stroke
- You have high blood pressure
- You suffer from blood circulation problems
- You have diabetes. When you start using Nicotinell Lozenges, you should monitor your blood sugar levels more frequently than usual. The need for insulin or your other diabetes medicine may change.
- You suffer from overactivity of the thyroid
- You have an adrenal gland tumor (pheochromocytoma)
- You have a renal or hepatic disease
- You suffer from inflammation of the esophagus, inflammation of the oral cavity or the throat, inflammation of the stomach or peptic ulcer
- You suffer/have suffered from epilepsy (convulsions)

## **Children and adolescents**

- Even small amounts of nicotine are dangerous for children and may lead to severe symptoms or death. Therefore, it is essential to keep Nicotinell Lozenges out of the reach and sight of children at all **times**. This medicine is not intended for use in children and adolescents under the age of 18.

## **Drug interactions**

**If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.**

- If you stop smoking and if you are using other medicines, your doctor may want to adjust the dosage of the medicines you take.

**There is no information available on drug interactions between Nicotinell Lozenges 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, such as:

- Theophylline (a medicine for the treatment of bronchial asthma)
- Tacrine (a medicine for the treatment of Alzheimer's disease)
- Olanzapine and clozapine (medicines for the treatment of schizophrenia)
- Insulin (a medicine for the treatment of diabetes) – the dosage may need to be adjusted

### **Use of the medicine and food**

Coffee, acidic and soft drinks may decrease the absorption of nicotine and therefore should be avoided 15 minutes before sucking the lozenge. Do not drink or eat while sucking the lozenge.

### **Pregnancy, breastfeeding and fertility**

#### **Pregnancy**

It is very important to stop smoking during pregnancy because smoking can slow the growth of your baby. Smoking may also lead to premature birth and even to a stillbirth. Ideally, it is best if you can give up smoking without the use of medicines. Nicotinell should only be used after consulting the medical staff.

#### **Breastfeeding**

Avoid using Nicotinell during breastfeeding, just as you should avoid smoking, because nicotine may be found in breast milk. If your doctor has recommended you to use Nicotinell Lozenges during breastfeeding, the lozenge should be sucked immediately after breastfeeding, and you should avoid sucking a lozenge for two hours before breastfeeding.

#### **Fertility**

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

### **Driving and operating machinery**

There is no evidence of risk associated with driving or operating machinery if the lozenge is taken according to the recommended dosage, however remember that smoking cessation can cause behavioral changes.

### **Important information about some of the ingredients of the medicine**

Nicotinell Lozenges contain sweeteners, including aspartame and maltitol.

Each lozenge contains aspartame which is a source of phenylalanine, which may be harmful to those who suffer from phenylketonuria (a rare genetic disease in which there is an accumulation of phenylalanine because it is not eliminated properly from the body).

Because Nicotinell Lozenges contain maltitol, which is a source of fructose:

- If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking the medicine.
- Patients may experience a mild laxative effect.

Nicotinell Lozenges ingredients are suitable for diabetic patients.

Nicotinell Lozenges contain 9.8 mg sodium per unit.

Patients who are on a sodium-controlled diet should take this into consideration.

## **3. How should you use the medicine?**

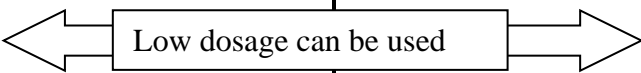
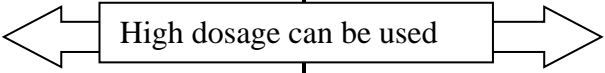
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Nicotinell Lozenges are available in two doses: 1 mg and 2 mg. The appropriate dose for you will depend on your previous smoking habits. You should use the 2 mg Nicotinell Lozenges if:

- You suffer from a high or very high nicotine dependence.
- You have previously tried to quit smoking with the 1 mg Nicotinell Lozenges and failed.
- The withdrawal symptoms that you experience remain so strong as to threaten relapse.

Otherwise, you should use the 1 mg Nicotinell Lozenges.

Choose your optimal dose according to the following table:

Low to moderate dependency	Moderate to high dependency	High or very high dependency
		
		
Less than 20 cigarettes a day	20-30 cigarettes a day	More than 30 cigarettes a day
The preferable product is 1 mg Nicotinell Lozenges.	Low dosage (1 mg Nicotinell Lozenges) or high dosage (2 mg Nicotinell Lozenges) can be used, according to your characteristics and preferences	The preferable product is 2 mg Nicotinell Lozenges.

If you experience a side effect as a result of using the high dose product (2 mg), consider using the low dose product (1 mg).

Method of use (for both doses):

1. Place one Nicotinell lozenge into your mouth and suck until you sense the taste of nicotine.
2. When you sense the taste of nicotine, move the lozenge to the side of the mouth, between your gum and the inner side of the cheek.
3. When the taste of nicotine weakens, suck the lozenge again.
4. Repeat these actions until the lozenge dissolves completely (about 30 minutes).

- ! Do not chew the lozenge.
- ! Do not swallow the lozenge whole.

The generally accepted dosage is:

Starting dosage: One lozenge, every 1-2 hours, when there is an urge to smoke. The accepted dosage is 8-12 lozenges a day.

Do not use more than 30 lozenges of the 1 mg Nicotinell Lozenges or 15 lozenges of the 2 mg Nicotinell Lozenges in a day.

Nicotinell lozenges are used primarily for smoking cessation.

Use for smoking cessation (stopping smoking completely):

To improve your chances of completely quitting smoking you have to stop smoking immediately upon starting to use Nicotinell Lozenges, and avoid smoking during the entire treatment period.

The recommended treatment duration differs from person to person. Usually the treatment should continue for at least 3 months. After 3 months of treatment you should gradually reduce the number of lozenges used each day. Stop the treatment when you manage to reduce your usage to 1-2 lozenges a day.

Generally, it is not recommended to use Nicotinell Lozenges for longer than 6 months. However, some ex-smokers may need a longer treatment to avoid returning to smoking.

**If you use Nicotinell Lozenges for more than nine months – you should consult a doctor.**

Counselling and guidance during the treatment with Nicotinell Lozenges may improve your chances of quitting smoking.

Use for smoking reduction:

Nicotinell Lozenges should be used between periods of smoking in order to prolong smoke-free intervals, with the intention of reducing smoking as much as possible.

The use of cigarettes should gradually be replaced by the use of lozenges. If after 6 weeks of using Nicotinell Lozenges you have not managed to reduce the number of cigarettes that you smoke daily to half the quantity, 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 start using Nicotinell Lozenges. After that, you should gradually reduce the number of lozenges you take, for example by reducing one lozenge from the daily total, 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.

In general, regular use of Nicotinell Lozenges for a period of over 6 months is not recommended. However, some ex-smokers may need a longer treatment to avoid returning to smoking.

Counselling and guidance during the treatment with Nicotinell Lozenges may improve your chances of quitting smoking.

- Always take Nicotinell Lozenges with you in case you feel the urge to smoke again.
- **Remember! One cigarette is enough for you to become a smoker again.**
- Do not exceed the recommended dose!
- This medicine is not intended for children under 18 years of age.

### **If you accidentally took a higher dosage**

Sucking too many lozenges may lead to the same symptoms as too much smoking. The general symptoms of an overdose of nicotine include:

Weakness, sweating, hypersalivation, burning throat, nausea, vomiting, diarrhea, abdominal pain, hearing and vision disturbance, headache, fast heartbeat or other disturbance in heart beats, shortness of breath and disturbance in blood circulation.

Consult the doctor or pharmacist if you experience any problem.

If you suspect a child has been poisoned, go to the doctor immediately. Even small amounts of nicotine are dangerous for children and may lead to severe symptoms and even to death.

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or the emergency room of a hospital immediately and take the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

## **4. Side effects**

As with any medicine, using Nicotinell Lozenges may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Allergic reactions to the preparation may rarely occur (in 1 to 10 out of every 10,000 users). In a handful of cases, the allergic reactions may be severe.

**Refer to the doctor immediately if you suffer from symptoms such as:**

- Swelling of the face, tongue and/or pharynx and/or difficulty swallowing, or hives (rash manifested by sudden appearance of itchy raised red patches on the skin) accompanied by breathing difficulties (angioedema).

Very common side effects (occur in more than 1 out of 10 users):

- Nausea

Common side effects (occur in up to 1 out of 10 users):

- Inflammation of the oral mucosa, discomfort in the oral cavity
- sore throat
- Vomiting
- Discomfort/pain in the stomach
- Diarrhea
- Digestive system disturbances/heartburn (Slower sucking will usually reduce the appearance of these problems)
- Flatulence
- Hiccups
- Constipation
- Dizziness and headache
- Insomnia

- Cough
- Dry mouth

Uncommon side effects (occur in up to 1 out of 100 users):

- Palpitations

Rare side effects (occur in up to 1 out of 1,000 users):

- Heart arrhythmias
- Allergic reactions

Side effects occurring at an unknown frequency:

- Hives
- Ulcerative inflammation of the oral cavity
- Tremor
- Breathing difficulties
- Difficulty swallowing
- Burping
- Hypersalivation
- Weakness
- Tiredness
- General malaise
- flu-like symptoms

Mouth ulcers may be related to smoking cessation, but the relation to the nicotine treatment is not clear.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Prevent poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions: Store at a temperature below 25°C.

## 6. Additional information

- In addition to the active ingredient, the medicine also contains:  
Nicotinell Lozenges 1 mg:  
Maltitol, Polyacrylate dispersion 30% (dry mass), Xanthan gum,  
Magnesium stearate, Sodium bicarbonate, Silica colloidal anhydrous,  
Aspartame, Sodium carbonate anhydrous, Peppermint oil, Levomenthol.

Nicotinell Lozenges 2 mg:  
Maltitol, Polyacrylate dispersion 30% (dry mass), Xanthan gum,  
Magnesium stearate, Sodium bicarbonate, Silica colloidal anhydrous,  
Aspartame, Sodium carbonate anhydrous, Levomenthol, Peppermint oil.

Every lozenge contains 10 mg aspartame and 9.8 mg sodium.

- What does the medicine look like and what are the contents of the package:  
Nicotinell Lozenge is a white, mint flavoured, round convex lozenge.

Nicotinell Lozenges packages contain 12, 36 or 96 lozenges in a package.

- Marketing authorization holder and address: GSK Consumer Healthcare Israel Ltd., P.O. Box 3256, Petah Tikva.
- Name and address of the manufacturer: GSK Consumer Healthcare Switzerland AG, Risch, Switzerland.
- This leaflet was reviewed and approved by the Ministry of Health in June 2017 and has been updated in accordance with the Ministry of Health guidelines in March 2022.
- Registration number of the medicine in the national drug registry of the Ministry of Health:  
Nicotinell Lozenges 1 mg: 136-54-31154  
Nicotinell Lozenges 2 mg: 139-97-31643

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*Nic Loz PT V2*