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Nicotine Mini Lozenge 4 mg

Please read this leaflet carefully before taking Nicotine Mini 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?

Nicotine Mini Lozenge belongs to a group of medicines which are used to help you stop smoking. The lozenges are available in HDPE bottle pack of 27 count and in blister pack of 10 count. Not all presentations may be available locally. Each lozenge contains nicotine 4 mg in the form of nicotine polacrilex.

Other ingredients are mannitol, xanthan gum, sodium alginate, povidone, hydroxypropyl cellulose, sodium carbonate, potassium bicarbonate, acesulfame potassium, sucralose, peppermint flavour, colloidal silicon dioxide and magnesium stearate.

The lozenge is sugar free.

Description of Nicotine Mini Lozenge

Nicotine Mini Lozenge 4 mg (Mint) are white to off white oval shaped lozenges debossed with “A435” on one side and plain on other side.

What you need to know about Nicotine Mini Lozenge?

Nicotine Mini 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. Nicotine Mini Lozenge 4 mg is best suited for those with high 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 Nicotine Mini Lozenge

Contains 4.66 mg 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 Nicotine Mini 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 nicotine replacement therapy (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. There is insufficient clinical data from controlled trials to recommend routine use in adolescents under the age of 18.

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, including non-nicotine smoking cessation drug and prescription medicine for depression or asthma, you should tell your doctor or pharmacist.

How to use Nicotine Mini 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 15 minutes before using or while the lozenge is in your mouth.

When starting treatment, use Nicotine Mini Lozenge 4 mg according to the following 12-week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 lozenge every 1 to 2 hours (Use at least 9 SKIIP Nicotine Mini Lozenge each day)	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

Do not use more than **5 lozenges** in 6 hours. Do not use more than **15 lozenges** per day.

If an adverse event occurs with the use of the higher dose form of Nicotine Mini 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.

Nicotine Mini Lozenge 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 10 - 20 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. Nicotine Mini 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 Nicotine Mini 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.

Stop use and ask a doctor if

- mouth problems occur
- persistent indigestion or severe sore throat occurs
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea,
- weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Further remarks

Do not use Nicotine Mini Lozenge after the expiry date shown on the label or on the lozenge blister. Store below 30°C. Protect from direct heat and sunlight. Keep out of reach of children. Keep the lozenge in HDPE containers / blister strip.

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Manufactured by:

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