



Read the entire insert / user guide carefully since it contains important information so that you can use it carefully in order to get the best results from it. Keep this leaflet; you may need to read it again. Consult your doctor or pharmacist if you need more information or advice. If you experience a side effect that worries you, or if you have a side effect not listed in this guide, please consult your doctor or pharmacist. Contact your doctor or pharmacist if you have not been able to stop smoking after 6 months of treatment with this product.

1. ABOUT THIS PRODUCT

Use:

This product is an instant release mouth mini lozenge providing fast relief from nicotine cravings. It is the quickest form of nicotine replacement therapy when you crave a cigarette or require relief when experiencing nicotine withdrawal symptoms.

What the product does:

This product provides fast relief of your nicotine cravings and the withdrawal symptoms you get when stopping smoking. When you suddenly stop providing nicotine from tobacco to your body, you will experience various unpleasant withdrawal symptoms. This product can prevent or reduce these cravings for smoking. This is because you continue to provide a small amount of nicotine to your body for a short period of time. The use of this product does not involve the health dangers associated with tobacco since it does not contain the tar, carbon monoxide and other toxins in cigarette smoke.

This product can greatly increase your success in quitting in combination with a support program and counselling.

2. WHAT TO DO BEFORE USING THIS PRODUCT (RISK INFORMATION AND CAUTIONS)

- A) Using other medications:
Consult your doctor or pharmacist if you are taking or have recently taken any other medication obtained without a prescription. This is especially important if you take medications containing:
- Theophylline to treat asthma
 - Clozapine for schizophrenia
 - Ropinirole to treat Parkinson's disease
- Consult your doctor before using this product if you have or have had heart, thyroid, circulation, stomach or mouth problems. High blood pressure, or if you are taking insulin or any prescription medicine.
Do not use for more than six (6) months without consulting a doctor
Discontinue using this product and consult your doctor if irregular heartbeat, chest pain or leg pain occurs or if severe persistent stomach upset (indigestion, heartburn) develops.
Consult your doctor if you have difficulty in reducing the quantity of nicotine
- B) Consult your dentist or doctor if injury or irritation to the mouth, teeth or gum around dentures occurs
- C) Keep out of reach of children and pets.
- D) Stop smoking, chewing tobacco or using snuff or any other nicotine replacement therapy products including patches before and while using this product since it may result in an overdose of nicotine. Do not use if you are an occasional non-smoker.
- E) Do not use if you are under 18 years of age (the use of this product for children and adolescents who smoke has not yet been evaluated)
- F) Do not use if you are allergic to nicotine or any of the non-medicinal ingredients in this product
- G) In case of overdose or if a child takes one or more nicotine mini-lozenges, contact your doctor or local poison control center at once. Children are especially sensitive to the effects of even small doses of nicotine. Symptoms of an overdose include nausea, abdominal pain, vomiting, diarrhea, cold sweat, dizziness, disturbed hearing and vision, mental confusion, rapid heartbeat, difficulty breathing and marked weakness

- H) Do not use if you are pregnant or breastfeeding a child. Do not get pregnant while using this product. If you think you are pregnant stop using this product and consult your doctor
- I) Do not use this product if you are an occasional smoker or non-smoker.

3. PRODUCT COMPOSITION

Medicinal ingredient in each dosage strength:

- Nic-Hit mini-lozenge 1mg contains 1mg of nicotine (as nicotine polacrilex).
- Nic-Hit mini-lozenge 2mg contains 2mg of nicotine (as nicotine polacrilex).
- Nic-Hit mini-lozenge 3mg contains 3mg of nicotine (as nicotine polacrilex).
- Nic-Hit mini-lozenge 4mg contains 4mg of nicotine (as nicotine polacrilex).

The non-medicinal ingredients in the product:

Corn Starch, Magnesium Stearate, Mannitol, Microcrystalline Cellulose, Flavour, Pea Starch, Sodium Carboxymethylcellulose, Sorbitol, Stearic Acid, Titanium Dioxide and Xylitol.

4. PROPER USE OF THIS PRODUCT

Always take this product as stated in this guide. You should check with your professional health care provider or pharmacist if you are not sure.

Individuals under 18 years of age should not use this [product unless prescribed by a doctor.

Stop smoking completely while using this product.

The following chart shows the recommended step by step process for taking this product

ADULT DOSE (OVER 18 YEARS OF AGE)

| Weeks 1-6 | Weeks 7-9 | Weeks 10-12 |
|-------------------------------------------------------|--------------------------------|--------------------------------|
| 1 mini-lozenge every 1-2 hours | 1 mini-lozenge every 2-4 hours | 1 mini-lozenge every 4-8 hours |
| Do not use more than 15 mini-lozenges per day. | | |

Cutting back on your usage of this product:

The purpose of using this product is to decrease and slowly eliminate your needs for nicotine, while controlling your cravings. You should gradually reduce the amount taken per day of this product. Some individuals find it easier to reduce by substituting ordinary sweets or sugar free candy for some of the product they would normally use.

You may be tempted to smoke again after treatment has stopped. If you have a craving, take one mini-lozenge. If one mini lozenge does not help within a few minutes, take a second mini lozenge.

IMPORTANT: Do not stop using this product if you do not like the taste at first. Most individuals get used to the taste after a few days.

How to administer this product:

This mini lozenge is formulated to deliver nicotine into your system through the lining of your mouth rather than in your stomach (like most other medications.) It is important to minimize the swallowing of the dissolved product so that it can be properly absorbed in your mouth.

1. Place the mini-lozenge in your mouth and allow it to slowly dissolve. Do not chew or swallow it. Although it is not harmful to you, it will not work as well.
2. Occasionally move the mini-lozenge from one side of the mouth to the other side until it is completely dissolved.

5. POSSIBLE SIDE EFFECTS

- This product can cause side effects, although not everyone gets them. This product can give the same side effects as other ways of taking nicotine. The side effects generally depend on the dose you take.
- You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. You may also experience these effects if you underuse this product before you are ready to reduce your nicotine intake.
- Usual side effects may include hiccups, headache, nausea, local tingling or burning sensation in the mouth, changes in taste perception, dryness or increased amounts of saliva in the mouth or throat or feelings of indigestion
- Common side effects may include irritability, aggression, impatience or frustration, anxiousness, restlessness, problem concentrating, sleep disturbance, increased appetite or weight gain, depression, urges to smoke, lowered heart rate, bleeding gums or dizziness
- Very common side effects may include hiccups, headache, nausea, local tingling or burning sensation in the mouth, changes in taste perception, dryness or increased amounts of saliva in the mouth or throat or feelings of indigestion
- Less common side effects may include cough, pain or discomfort in the abdomen or chest, vomiting, flatulence or diarrhea, tightness or numbness of the throat and fatigue.
- Rare side effects may include running nose, stuffiness, sneezing/wheezing (bronchospasm), bleeding, changes in how things smell, effort to breathe (dyspnea), skin flushing, cold sweat, eye irritation/ increased tear production. Pain/ tension or discomfort in muscles or joints, toothache,

inflammation of the tongue or gums, damage to lining of the mouth, changes in sound of your voice, palpitations or fast heart rate, decreased appetite, hypersensitivity (allergy) including rash and / or itching (pruritus, urticarial)

- When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.
- If you experience a side effect that worries you, or if you have a side effect not listed in this guide, tell your professional health care provider or pharmacist.

6. STORAGE CONDITIONS

Do not use this product after the expiry date stated on the package. Do not use if the induction seal is torn, punctured, or shows evidence of tampering. Store between 15-25oC (59-77oF). Protect from light.

7. PRODUCT AVAILABILITY

The product is available in various flavors in a 20 mini-lozenges blister package

8. MORE INFORMATION

Questions about Nic-Hit mini-lozenge: 1-888-929-0835

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