

## INSERT / USER GUIDE

# Nic-Hit

## FAST ACTING STOP SMOKING AID

1 mg of NICOTINE per spray

2 mg of NICOTINE per spray

## Oromucosal Spray Mist

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 spray 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:  
Tell 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 sprays of this product, 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 liquid spray 1mg contains 1mg of nicotine
- Nic-Hit liquid spray 2mg contains 2mg of nicotine

#### The non-medicinal ingredients in the product:

Propylene glycol, glycerol, xylitol, flavor and purified water

### 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)

1 mg Nic-Hit spray	2 mg Nic-Hit spray
<b>Step #1: weeks 1-6</b>	
Spray 1-2 doses, 1-24 times a day, of 1 mg Nic-Hit liquid into your mouth, whenever you would normally smoke a cigarette or have cravings for a cigarette. Use the second spray if your cravings do not disappear within a few minutes. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays. The maximum daily dose is 48 sprays per day providing up to 48 mg of nicotine.	Spray 1 dose, 1-24 times a day, of 2 mg Nic-Hit liquid into your mouth, whenever you would normally smoke a cigarette or have cravings for a cigarette. The maximum daily dose is 24 sprays per day providing up to 48 mg of nicotine.

#### Step #2: weeks 7-9

Start reducing the number of sprays per day. By the end of week 9 you should be using half the average number of sprays per day that you used in step #1.	Start reducing the number of sprays per day. By the end of week 9 you should be using half the average number of sprays per day that you used in step #1.
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#### Step #3: weeks 10-12

Continue reducing the number of sprays per day so that you are not using more than 2-4 sprays per day during week 12. At the end of week 12, stop using the Nic-Hit spray	Continue reducing the number of sprays per day so that you are not using more than 2-4 sprays per day during week 12. At the end of week 12, stop using the Nic-Hit spray.
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#### 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 use 1 spray of either the 1mg or 2mg of this product, if one spray does not help within a few minutes, use 2 sprays.

**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:

- Remove the cap and the inner seal of the bottle.
- Remove cellophane packaging of the spray assembly.
- Screw the spray assembly to the bottle.
- Press the top of the spray assembly to produce one spray of the solution, aim directly in the oral cavity (mouth) towards the upper palette. Avoiding the spray from touching your lips. To avoid the solution from reaching your throat, do not inspire at the time of vaporization of the product You may feel hot or tingling sensation. This is a sign that this product is working. For best results, refrain from swallowing your saliva for a few seconds after spraying.



- Replace the protective cap on the spray assembly after use

### 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.
- 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

This product is available in various flavors packaged in 30mL per bottle for each strength.

**Manufactured by Euro-Pharm International Canada Inc.  
for Nic-Hit International Inc.  
Montreal (Quebec) Canada H1P 3H8  
www.Nic-Hit.com • 1-888-929-0835**