

**GOOD SENSE NICOTINE - nicotine polacrilex lozenge**  
**Dispensing Solutions, Inc.**

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**Perrigo Nicotine Lozenge Drug Facts**

**Active ingredient (in each lozenge)**

Nicotine polacrilex, 2 mg (nicotine)

**Purpose**

Stop smoking aid

**Uses**

- reduces withdrawal symptoms, including nicotine craving associated with quitting smoking

**Warnings**

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**If you are pregnant or breast-feeding,**

only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

**Do not use**

- if you continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine containing products

**Ask a doctor before use if you have**

- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- stomach ulcer or diabetes

**Ask a doctor or pharmacist before use if you are**

- using a non-nicotine stop smoking drug
- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

**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 or rapid heartbeat

**Keep out of reach of children and pets.**

Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it in paper and throw away in the trash. In case of overdose, get medical help or contact a

Poison Control Center right away.

### Directions

- if you are under 18 years of age, ask a doctor before use
- before using this product, read the enclosed User's Guide for complete directions and other important information
- stop smoking completely when you begin using the lozenge
- if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine lozenge
- if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine lozenge 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	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

- nicotine lozenge is a medicine and must be used a certain way to get the best results
- place the lozenge in your mouth and allow the lozenge to slowly dissolve (about 20-30 minutes). Minimize swallowing. Do not chew or swallow lozenge.
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20-30 minutes)
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.
- stop using the nicotine lozenge at the end of 12 weeks. If you still feel the need to use nicotine lozenges, talk to your doctor.

### Other information

- each lozenge contains: sodium 15 mg
- Phenylketonurics: Contains Phenylalanine 5.1 mg per lozenge
- sugar alcohol content: 1 g mannitol per lozenge
- store at 20-25°C (68-77°F)
- keep vial closed and protect from light

### Inactive ingredients

aspartame, flavor, magnesium stearate, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum

### Questions or comments?

call toll-free 1-866-751-9303

### Principal Display Panel

BULK SOURCE DATA  
 DIST. BY: PERRIGO  
 ALLEGAN, MI 49010  
**PRODUCT ID:**  
 GOLD / WHITE / BLACK / YELLOW /  
 GREEN / NAVY BLUE / MINT GREEN /  
 RED / ORANGE / BLUE BOX  
 PRINTED NDC 0113-0344-05  
 BULK SOURCE NDC: 00113-0344-05  
 MFR. LOT: XXXXXX  
 PEDIGREE #: 20681192  
 DISPENSE IN THIS  
 TIGHT/LIGHT RESISTANT CONTAINER



WARNING: KEEP OUT OF  
 CHILDREN'S REACH  
**STORE AT 68°- 77° F. SEE USP.**

7N0872 NDC 68258-7991-07  
 NICOTINE POLACRILEX 2 mg  
 72 LOZENGES  
 LOT # SAMPLE EXP: 00-00  
 MN 00113-0344-05 RX# 26009055

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**NICOTINE POLACRILEX 2 mg**  
**72 LOZENGES**  
**NDC 68258-7991-07**  
**PRODUCT # 7N0872**

Rev. Date: 01/12

**ACTIVE INGREDIENT**  
 (IN EACH LOZENGE):  
 NICOTINE POLACRILEX 2 mg (NICOTINE)  
**PURPOSE: STOP SMOKING AID**  
 FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE  
 MORE THAN 30 MINUTES AFTER WAKING UP.  
 MINT FLAVOR.

**COMPARE TO COMMIT ACTIVE INGREDIENT**  
 LOT#SAMPLE EXP: 00-00 Rx # 26009055



Packaged Exclusively By:  
**DISPENSING SOLUTIONS** Inc.  
 Santa Ana, CA 92704

PLACE ONE LOZENGE IN  
 YOUR MOUTH EVERY \_\_\_\_\_ HOURS  
 AS DIRECTED. ALLOW LOZENGE  
 TO SLOWLY DISSOLVE. DO NOT  
 CHEW OR SWALLOW. READ THE  
 ENCLOSED USER'S GUIDE FOR  
 COMPLETE DIRECTIONS AND  
 OTHER IMPORTANT INFORMATION.

NDC 68258-7991-07

<b>GOOD SENSE NICOTINE</b>			
nicotine polacrilex lozenge			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68258-7991(NDC:0113-0344)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg	
<b>Inactive Ingredients</b>			
Ingredient Name	Strength		
ASPARTAME (UNII: Z0H242BBR1)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MANNITOL (UNII: 3OWL53L36A)			
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)			
SODIUM ALGINATE (UNII: C269C4G2ZQ)			
SODIUM CARBONATE (UNII: 45P3261C7T)			
XANTHAN GUM (UNII: TTV12P4NEE)			
<b>Product Characteristics</b>			
<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16 mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	L344
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68258-7991-7	3 in 1 CARTON		
1		24 in 1 VIAL		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077007	11/28/2009	

**Labeler** - Dispensing Solutions, Inc. (066070785)**Registrant** - PSS World Medical, Inc. (101822682)**Establishment**

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel, repack

Revised: 3/2012

Dispensing Solutions, Inc.