

**NICOTINE ORIGINAL- nicotine polacrilex lozenge**

**NICOTINE- nicotine polacrilex lozenge**

**Walgreens**

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**Drug Facts**

***Active ingredient (in each lozenge) 2mg***

Nicotine polacrilex, 2 mg

***Active ingredient (in each lozenge) 4mg***

Nicotine polacrilex, 4 mg

***Purpose***

Stop smoking aid

***Use***

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

***Warnings***

**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 and 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 (2mg Lozenge )**

- **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 4mg nicotine lozenge**
- **if you smoke your first cigarette more than 30 minutes after waking up, use 2mg 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.

**Directions (4mg Lozenge)**

- **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 more than 30 minutes after waking up, use 2mg nicotine lozenge**
- **if you smoke your first cigarette within 30 minutes of waking up, use 4mg 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 (Original)***

- **each lozenge contains:** sodium, 18 mg
- Phenylketonurics: Contains Phenylalanine 3.4 mg per lozenge
- store at 20 – 25°C (68 – 77°F)
- protect from light

#### ***Other Information (Cherry)***

- **each lozenge contains:** sodium, 18mg
- store at 20 - 25°C (68 - 77°F)
- keep vial tightly closed and protect from light

#### ***Other information (Mint)***

- each lozenge contains: sodium, 18mg
- Phenylketonurics: Contains Phenylalanine 3.4 mg per lozenge
- store at 20 - 25°C (68 - 77°F)
- keep vial tightly closed and protect from light

#### ***Inactive ingredients (Original)***

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

#### ***Inactive ingredients (Cherry)***

acesulfame potassium, benzyl alcohol, butylhydroxy toluene, calcium polycarbophil, coconut and/or palm kernel oil, eugenol, flavors, magnesium stearate, maltodextrin, mannitol, modified corn starch, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum

***Inactive ingredients (Mint)***

acacia, aspartame, calcium polycarbophil, corn syrup solids, flavors, lactose, magnesium stearate, maltodextrin, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, soy protein, triethyl citrate, xanthan gum

***Questions or comments?***

call toll-free **1-877-306-0019** (English/Spanish) weekdays (9:00 am – 4:30 pm ET)

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**Principal Display Panel**

**NDC 0363-0209-01**

**Nicotine Lozenge**

**Walgreens**

**Nicotine Polacrilex Lozenge, 4mg**

**STOP SMOKING AID**

**Original Flavor**

**72 LOZENGES**

**4mg EACH**

**Compare to Nicorette®\* Lozenge**

Includes User's Guide

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette MORE THAN 30 MINUTES after waking up, use Nicotine Polacrilex Lozenge, 2mg

- **not for sale to those under 18 years of age**
- **proof of age required**
- **not for sale in vending machines or from any source where proof of age cannot be verified**

This product is protected in sealed blisters.

**Do not use if individual blisters or printed backings are broken, open or torn.**

**TO INCREASE YOUR SUCCESS IN QUITTING:**

- You must be motivated to quit.
- **Use Enough** – Use **at least 9 lozenges** per day during the first six weeks.
- **Use Long Enough** – Use for the full 12 weeks.
- **Use With a Support Program** as directed in the enclosed User's Guide.

To remove the lozenge, tear off single unit.

Peel off backing starting at corner with loose edge.

Push lozenge through foil.

Comments/questions:

GCSP 5.4376.4C Re: Consumer Relations, PO Box 13398

Research Triangle Park, NC 27709-9627

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NDC 0363-0209-01

Compare to Nicorette®\* Lozenge

*Walgreens*

# Nicotine Lozenge

Nicotine Polacrilex Lozenge, 4mg

**STOP SMOKING AID**

**4mg**

Includes User's Guide

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THEIR FIRST CIGARETTE  
WITHIN 30 MINUTES  
OF WAKING UP.**

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**Original Flavor**



**72 LOZENGES  
4mg EACH**

Principal Display Panel

NDC 0363-0208-01

Nicotine Lozenge

Walgreens

**Nicotine Polacrilex Lozenge, 2mg**

**STOP SMOKING AID**

**Original Flavor**

**72 LOZENGES**

**2mg EACH**

**Compare to Nicorette®\* Lozenge**

Includes User's Guide

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NDC 0363-0208-01

Compare to Nicorette®\* Lozenge

*Walgreens*

# Nicotine Lozenge

Nicotine Polacrilex Lozenge, 2mg

**STOP SMOKING AID**

**2mg**

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THEIR FIRST CIGARETTE  
MORE THAN 30 MINUTES  
AFTER WAKING UP.**

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**Original Flavor**



**72 LOZENGES  
2mg EACH**

Principal Display Panel

NDC 0363-9200-02

Nicotine Lozenge

Walgreens



**Nicotine Polacrilex Lozenge, 4mg**

**STOP SMOKING AID**

**Cherry Flavor**

**72 LOZENGES, 4mg EACH** (3 Vials of 24)

**Compare to Nicorette®\* Lozenge**

Includes User's Guide

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette MORE THAN 30 MINUTES after waking up, use Nicotine Polacrilex Lozenge, 2mg

- **not for sale to those under 18 years of age**
- **proof of age required**
- **not for sale in vending machines or from any source where proof of age cannot be verified**

**TAMPER EVIDENT FEATURE:** Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken.

Retain outer carton for full product uses, directions and warnings.

**TO INCREASE YOUR SUCCESS IN QUITTING:**

- You must be motivated to quit.
- **Use Enough** – Use **at least 9 lozenges** per day during the first six weeks.
- **Use Long Enough** – Use for the full 12 weeks.
- **Use With a Support Program** as directed in the enclosed User's Guide.

To open vial, push in child resistant band on the vial with thumb.

Flip up the top of the vial and remove lozenge. A small amount of powder on opening of the vial is normal.

Comments/questions:

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NDC 0363-9200-02

Compare to Nicorette®\* Lozenge

*Walgreens*

# Nicotine Lozenge

Nicotine Polacrilex Lozenge, 4mg



**STOP SMOKING AID**

**4mg**

Includes User's Guide

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THEIR FIRST CIGARETTE  
WITHIN 30 MINUTES  
OF WAKING UP.**

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MORE THAN 30 MINUTES after  
waking up, use Nicotine Polacrilex  
Lozenge, 2mg

**Cherry Flavor**



**72 LOZENGES, 4mg EACH**  
(3 Vials of 24)

Principal Display Panel

NDC 0363-0446-02

Nicotine Lozenge

Walgreens

**Nicotine Polacrilex Lozenge, 2mg**

**STOP SMOKING AID**

**Cherry Flavor**

**72 LOZENGES, 2mg EACH** (3 Vials of 24)

**Compare to Nicorette®\* Lozenge**

Includes User's Guide

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

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Comments/questions:

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NDC 0363-0446-02

Compare to Nicorette®\* Lozenge

*Walgreens*

# Nicotine Lozenge

Nicotine Polacrilex Lozenge, 2mg

**STOP SMOKING AID**



**2mg**

Includes User's Guide

**FOR THOSE WHO SMOKE  
THEIR FIRST CIGARETTE  
MORE THAN 30 MINUTES  
AFTER WAKING UP.**

If you smoke your first cigarette  
WITHIN 30 MINUTES of waking up,  
use Nicotine Polacrilex Lozenge, 4mg

**Cherry Flavor**



**72 LOZENGES, 2mg EACH**  
(3 Vials of 24)

Principal Display Panel

NDC 0363-9171-02

Nicotine Lozenge

Walgreens

**Nicotine Polacrilex Lozenge, 4mg**

**STOP SMOKING AID**

**Mint Flavor**

**72 LOZENGES, 4mg EACH** (3 Vials of 24)

**Compare to Nicorette®\* Lozenge**

Includes User's Guide

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

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Comments/questions:

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NDC 0363-9171-02

Compare to Nicorette®\* Lozenge

*Walgreens*

# Nicotine Lozenge

Nicotine Polacrilex Lozenge, 4mg

**STOP SMOKING AID**



**4mg**

Includes User's Guide

**FOR THOSE WHO SMOKE  
THEIR FIRST CIGARETTE  
WITHIN 30 MINUTES  
OF WAKING UP.**

If you smoke your first cigarette  
MORE THAN 30 MINUTES after  
waking up, use Nicotine Polacrilex  
Lozenge, 2mg

**Mint Flavor**



**72 LOZENGES, 4mg EACH**  
(3 Vials of 24)

Principal Display Panel

NDC 0363-9170-02

Nicotine Lozenge

Walgreens

**Nicotine Polacrilex Lozenge, 2mg**

**STOP SMOKING AID**

**Mint Flavor**

**72 LOZENGES, 2mg EACH** (3 Vials of 24)

**Compare to Nicorette®\* Lozenge**

Includes User's Guide

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette WITHIN 30 MINUTES of waking up, use Nicotine Polacrilex Lozenge, 4mg

- **not for sale to those under 18 years of age**
- **proof of age required**
- **not for sale in vending machines or from any source where proof of age cannot be verified**

**TAMPER EVIDENT FEATURE:** Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken.

Retain outer carton for full product uses, directions and warnings.

**TO INCREASE YOUR SUCCESS IN QUITTING:**

- You must be motivated to quit.
- **Use Enough** – Use **at least 9 lozenges** per day during the first six weeks.
- **Use Long Enough** – Use for the full 12 weeks.
- **Use With a Support Program** as directed in the enclosed User's Guide.

To open vial, push in child resistant band on the vial with thumb.

Flip up the top of the vial and remove lozenge. A small amount of powder on opening of the vial is normal.

Comments/questions:

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NDC 0363-9170-02

Compare to Nicorette®\* Lozenge

*Walgreens*

# Nicotine Lozenge

Nicotine Polacrilex Lozenge, 2mg

**STOP SMOKING AID**



**2mg**

Includes User's Guide

FOR THOSE WHO SMOKE  
THEIR FIRST CIGARETTE  
MORE THAN 30 MINUTES  
AFTER WAKING UP.

If you smoke your first cigarette  
WITHIN 30 MINUTES of waking up,  
use Nicotine Polacrilex Lozenge, 4mg

*Mint Flavor*



**72 LOZENGES, 2mg EACH**  
(3 Vials of 24)

**NICOTINE ORIGINAL**

nicotine polacrilex lozenge

**Product Information**



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0209
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

### Inactive Ingredients

Ingredient Name	Strength
POLACRILIN (UNII: RCZ785HI7S)	
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM POLYCARBO PHIL (UNII: 8F049NKY49)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	PL4
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0209-01	6 in 1 CARTON	10/31/2002	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-0209-07	9 in 1 CARTON	10/31/2002	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021330	10/31/2002	

## NICOTINE ORIGINAL

nicotine polacrilex lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0208
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
POLACRILIN (UNII: RCZ785HI7S)	
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM POLYCARBO PHIL (UNII: 8F049NKY49)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	PL2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0208-01	6 in 1 CARTON	10/31/2002	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-0208-07	9 in 1 CARTON	10/31/2002	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021330	10/31/2002	

## NICOTINE

nicotine polacrilex lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-9200
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

**Inactive Ingredients**

Ingredient Name	Strength
POLACRILIN (UNII: RCZ785HI7S)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PALM KERNEL OIL (UNII: B0S90M0233)	
EUGENOL (UNII: 3T8H1794QW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	PL4C
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9200-02	3 in 1 CARTON	07/14/2011	
1		24 in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0363-9200-03	4 in 1 CARTON	07/14/2011	
2		27 in 1 CONTAINER; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021330	07/14/2011	

# NICOTINE

nicotine polacrilex lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0446
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
POLACRILIN (UNII: RCZ785HI7S)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PALM KERNEL OIL (UNII: B0S90M0233)	
EUGENOL (UNII: 3T8H1794QW)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	PL2C
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0446-02	3 in 1 CARTON	07/14/2011	
1		24 in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0363-0446-03	4 in 1 CARTON	07/14/2011	
2		27 in 1 CONTAINER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021330	07/14/2011	

## NICOTINE

nicotine polacrilex lozenge

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9171
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

### Inactive Ingredients

Ingredient Name	Strength
POLACRILIN (UNII: RCZ785HI7S)	
ACACIA (UNII: 5C5403N26O)	
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49)	
CORN SYRUP (UNII: 9G5L16BK6N)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SOY PROTEIN (UNII: R44IWB3RN5)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	ROUND	Size	16mm
Flavor	MINT	Imprint Code	PL4S
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9171-02	3 in 1 CARTON	07/14/2011	
1		24 in 1 CONTAINER; Type 0: Not a Combination Product		

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021330	07/14/2011	

NICOTINE			
nicotine polacrilex lozenge			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9170
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg
Inactive Ingredients			
	Ingredient Name		Strength
	POLACRILIN (UNII: RCZ785HI7S)		
	ACACIA (UNII: 5C5403N26O)		
	ASPARTAME (UNII: Z0H242BBR1)		
	CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49)		
	CORN SYRUP (UNII: 9G5L16BK6N)		
	LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
	MAGNESIUM STEARATE (UNII: 70097M6I30)		
	MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
	MANNITOL (UNII: 3OWL53L36A)		
	POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)		
	SODIUM ALGINATE (UNII: C269C4G2ZQ)		
	SODIUM CARBONATE (UNII: 45P3261C7T)		
	SOY PROTEIN (UNII: R44IWB3RN5)		
	TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		
	XANTHAN GUM (UNII: TTV12P4NEE)		
Product Characteristics			
Color	WHITE (white to off-white)	Score	no score
Shape	ROUND	Size	16mm
Flavor	MINT	Imprint Code	PL2S
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9170-02	3 in 1 CARTON	07/14/2011	
1		24 in 1 CONTAINER; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021330	07/14/2011	

**Labeler** - Walgreens (008965063)**Registrant** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

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