NICOTINE POLACRILEX COATED MINT- nicotine polacrilex gum, chewing Chain Drug Consortium, LLC

Nicotine Polacrilex Gum 2 mg and 4 mg Coated Mint - Premier Value (Chain Drug Consortium, LLC)

Drug Facts

Active ingredient (in each chewing piece) - 2 mg

Nicotine Polacrilex 2 mg (nicotine)

Active ingredient (in each chewing piece) - 4 mg

Nicotine Polacrilex 4 mg (nicotine)

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.

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 blood pressure.
- stomach ulcer or diabetes
- history of seizures

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, teeth, or jaw problems occur
- 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)

Keep out of reach of children and pets.

Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions - 2 mg

- 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
- begin using the gum on your quit day
- if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine gum
- if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every	1 piece every	1 piece every
1 to 2 hours	2 to 4 hours	4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

Other information - 2 mg

- each piece contains: calcium 115 mg, sodium 8 mg
- store at 20 25°C (68 77°F)
- protect from light

Directions - 4 mg

- 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
- begin using the gum on your quit day
- if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum
- if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine gum according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every	1 piece every	1 piece every
1 to 2 hours	2 to 4 hours	4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

Other information - 4 mg

- each piece contains: calcium 120 mg, sodium 8 mg
- store at 20 25°C (68 77°F)
- protect from light

Inactive ingredients - 2 mg

acacia, acesulfame potassium, carnauba wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol.

Inactive ingredients - 4 mg

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol.

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal display panel 2 mg

COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® GUM*

Nicotine Polacrilex Gum USP, 2 mg (nicotine)

STOP SMOKING AID

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

If you smoke your first cigarette <u>WITHIN</u> 30 MINUTES of waking up, use Nicotine Polacrilex Gum USP, 4 mg

COATED MINT 2 mg

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.

2. **Use Enough** - Chew **at least 9 pieces** of Nicotine Polacrilex Gum per day during the first six weeks.

3. Use Long Enough - Use Nicotine Polacrilex Gum for the full 12 weeks.

4. Use with a Support Program as directed in the enclosed User's Guide.

- 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 not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® Gum.

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN.

Distributed By:

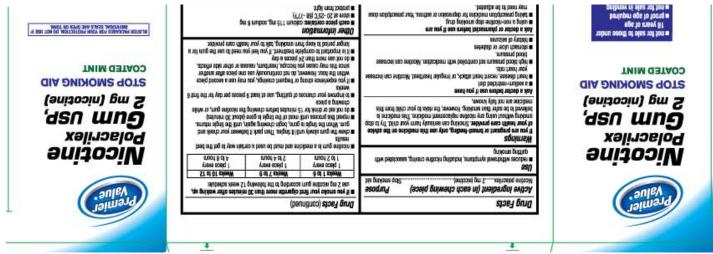
Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

Package label 2 mg 284





PREMIER VALUE Nicotine Gum Coated Mint

Package label 2 mg 280



PRIMIER VALUE Nicotine Gum Coated Mint

Package label 2 mg 559

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit Use Enough - Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks.

Use Long Enough - Use Nicotine Polacrilex Gum for the full 12 weeks.
 Use With a Support Program as directed in the enclosed User's Guide.



PREMIER VALUE Nicotine Polacrilex Gum Coated Mint Flavor

Principal display panel 4 mg

COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® GUM*

Nicotine Polacrilex Gum USP, 4 mg (nicotine)

STOP SMOKING AID

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 Gum USP, 2 mg

COATED MINT 4 MG

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.

2. **Use Enough** - Chew **at least 9 pieces** of Nicotine Polacrilex Gum per day during the first six weeks.

- 3. Use Long Enough Use Nicotine Polacrilex Gum for the full 12 weeks.
- 4. Use With a Support Program as directed in the enclosed User's Guide
- 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 required

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® Gum

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN.

Distributed By:

Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

Package label 4 mg 560

TO INCREASE YOUR SUCCESS IN QUITTING:

- 1. You must be motivated to guit. Use Enough - Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks.
- Use Long Enough Use Nicotine Polacrilex Gum for the full 12 weeks.
 Use With a Support Program as directed in the enclosed User's Guide.



PREMIER VALUE Nicotine Polacrilex Gum Coated Mint

Package label 4 mg 285



 Proof of age required. 	It satisfies the same state of the same same same same same same same sam	insibergin veritseni jelei muniutis 01± wolay mulae abao mulaamen	a, tawara, gum bese, frydn		
■ Not for sale to those	where a cordox or phasemetric before use if you are the second prescription medicine for your group of the before the conditioner and the second of the major to boar adjusted for the second of the second of the second of the second of the major second of the second	Other information a such piece cardinating ca a such piece cardinating ca a such such that a such such that a such such that a such such that a such such such such such such such such	caldium 120 mg, sodium 8	6u (A 1951 TON GO, JODITZITONA BLOY ROY OD OZOANSAN MITZLAN HIGT TON GO, JODITZITONA BLOY ROY OD OZOANSAN MITZLAN
A mg (nicotine) A mg (nicotine) OIA DINOMING AID COATED MINT	As a four deal region of your have as souther-restricted for the purple mitted despise, resert theat faitack or imgular heartheat. Noothe can increase which blood preserm can blood measure. mission of anotheat and the purple mission of anotheat mission	seles the process of the process of the since the may cause you by not use on the process of the important to complet minimode the process of the since of the sinc	g or frequent crawhoge, you er, do not continuously ua ou hisoupe, hoartburn, na Manuel a de Manuel a	one biece siter another sea or other side affords. The need to use the gum for a	Атар (nicotine) STOP SMOKING AID совтер минт
Aicotine ^{xalinasloq}	Marthings and a set of the set of	ctrewing a piece a do not eat or drink for 15 grav When the brocess until grave the gum stowly un results results	riti it tingles. Then pair it tin s gore, begin chrewing ag an insist of the tingle is gon the check endes before chewin 15	ins steerly rury naewted Ar until the diago mitume, a ytuout 30 mitutes articoin articoin artig	Aicotine Polacrilex Geu mu Ə
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Caimard	Active ingredient (in each chewing piece) Purpose Micrine polantert mg (niosm)		w ST primolet art of prib	selv schedule:	Premier
	spoey brug	nutuoo) spary fining	(090)		

Package label 4 mg 281



PREMIER VALUE Nicotine Gum Coated Mint

NICOTINE POLACRIL nicotine polacrilex gum, chew Product Information		NT	
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-280
Route of Administration	BUCCAL		

	lient/Active Mo	iety				
	Ingredien	t Name		Basis of Stren	ngth	Strength
NICOTINE (UNII: 6	M3C89ZY6R) (NICOT	INE - UNII:6M3C89ZY6R)		NICOTINE		2 mg
nactive Ingr	edients					
		Ingredient Name				Strength
ACACIA (UNII: 5C5	TASSIUM (UNII: 230	\/720560\				
	(UNII: R12CBM0EIZ)	V/3Q3G9)				
		PECIFIED (UNII: 9XZ8H6N	16OH)			
	DE (UNII: 3A3U0GI71)		,			
	ONATE (UNII: 8MDF5)					
	IATE (UNII: 45P32610					
TALC (UNII: 7SEV7	'J4R1U)					
LITANIUM DIOXIC	DE (UNII: 15FIX9V2JP)					
KYLITOL (UNII: VC	Q006KQ1E)					
Product Chai	acteristics					
Color	white		Score		no s	core
Shape	SQUARE		Size		14m	m
Flavor	MINT (coated r	nint)	Imprint	Code		
Contains						
Contains						
Packaging	Packa	ge Description	м	arketing Start Date	Mark	eting End Date
Packaging # Item Code	Packa 4 in 1 CARTON	ge Description		-	Mark	
Hermitian Hermitian Item Code NDC:68016- 280-49	4 in 1 CARTON	ige Description CK; Type 0: Not a Combin	07/0	Date	Mark	eting End Date
Packaging # Item Code 1 NDC:68016-	4 in 1 CARTON 10 in 1 BLISTER PA		07/0	Date	Mark	
Item Code NDC:68016- 280-49	4 in 1 CARTON 10 in 1 BLISTER PA	CK; Type 0: Not a Combin	07/0	Date	Mark	
Item Code NDC:68016- 280-49	4 in 1 CARTON 10 in 1 BLISTER PA Product	CK; Type 0: Not a Combin	07/0	Date		

NICOTINE POLACRILEX COATED MINT nicotine polacrilex gum, chewin Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-284

Active Ingred	lient/Active Moiety				
	Ingredient Name		Basis of Stre	ength	Strength
NICOTINE (UNII: 6	M3C89ZY6R) (NICOTINE - UNII:6M30	C89ZY6R)	NICOTINE	-	2 mg
Inactive Ingre	edients				
	Ingredient	Name			Strength
ACACIA (UNII: 5C5	403N26O)				
	TASSIUM (UNII: 230V73Q5G9)				
	(UNII: R12CBM0EIZ)				
	CELLULOSE, UNSPECIFIED (UN	II: 9XZ8H6N6OH)			
	DE (UNII: 3A3U0GI71G)				
	DNATE (UNII: 8MDF5V39QO)				
	IATE (UNII: 45P3261C7T)				
ALC (UNII: 75EV7	•				
ritanium dioxid (Ylitol (Unii: VC)	DE (UNII: 15FIX9V2JP)				
	acteristics	Score		no s	core
		Score		no s	core
Color	acteristics	Score Size		no s 14m	
Color Shape	white	Size	nt Code		
Color Shape Flavor	racteristics white SQUARE	Size			
Color Shape Flavor	racteristics white SQUARE	Size			
Color Shape Flavor Contains	racteristics white SQUARE	Size	nt Code	14m	m
Color Shape Flavor Contains Packaging	racteristics white SQUARE	Size Impri		14m	
Color Shape Flavor Contains Packaging # Item Code	racteristics white SQUARE MINT (coated mint)	Size Impri	nt Code Marketing Start	14m	m a eting End
Color Shape Flavor Contains Packaging # Item Code I NDC:68016- 284-44	Package Descrip	Size Impri	nt Code Marketing Start Date	14m	m a eting End
Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 284-44	Package Description 10 in 1 CARTON 10 in 1 BLISTER PACK; Type 0: Notest	Size Impri	nt Code Marketing Start Date	14m	m eting End
Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 284-44	Package Description 10 in 1 CARTON 10 in 1 BLISTER PACK; Type 0: Notest	Size Impri	nt Code Marketing Start Date	14m	m a eting End
 NDC:68016- 284-44 NDC:68016- NDC:68016-	white SQUARE MINT (coated mint) Package Descript 10 in 1 CARTON 10 in 1 BLISTER PACK; Type 0: Not Product	otion Size Impri ot a Combination	nt Code Marketing Start Date	14m	m a eting End

NICOTINE POLACRILEX COATED MINT

nicotine polacrilex gum, chewing

Product Information

Product Type		HUMAN OTC DRUG	Item Co	ode (Source)	NDC:68016-281
Route of Admin	nistration	BUCCAL			
Active Ingred	lient/Active	Moietv			
		lient Name		Basis of Str	ength Strength
	-	COTINE - UNII:6M3C89ZY6	R)	NICOTINE	4 mg
				NICOTINE	- mg
Inactive Ingr	edients				
mactive mgr	cultures	Ingredient Name			Strength
ACACIA (UNII: 5C5	403N26O)				
ACESULFAME PO	TASSIUM (UNII:	230V73Q5G9)			
CARNAUBA WAX	(UNII: R12CBM0E	EIZ)			
D&C YELLOW NO	. 10 (UNII: 355)	V5USQ3G)			
HYDROXYPROPY	L CELLULOSE,	UNSPECIFIED (UNII: 9XZ8	H6N6OH)		
MAGNESIUM OXI	DE (UNII: 3A3U0	GI71G)			
SODIUM BICARBO	ONATE (UNII: 8M	1DF5V39QO)			
SODIUM CARBON	IATE (UNII: 45P3	261C7T)			
TALC (UNII: 7SEV7	J4R1U)				
TITANIUM DIOXIC	-	/2JP)			
XYLITOL (UNII: VC					
Product Char	acteristics				
	acteristics				
Color	yellow		Score	•	no score
			Score Size	•	no score 14mm
Color	yellow SQUARE	ted mint)	Size		
Color Shape Flavor	yellow	ted mint)	Size	e nt Code	
Color Shape	yellow SQUARE	ted mint)	Size		
Color Shape Flavor	yellow SQUARE	ted mint)	Size		
Color Shape Flavor Contains	yellow SQUARE	ted mint)	Size		
Color Shape Flavor	yellow SQUARE	ted mint)	Size	nt Code	14mm
Color Shape Flavor Contains	yellow SQUARE MINT (coa	ted mint) ackage Description	Size		
Color Shape Flavor Contains Packaging	yellow SQUARE MINT (coa	ckage Description	Size	nt Code Marketing Start	14mm Marketing End
Color Shape Flavor Contains Packaging # Item Code	yellow SQUARE MINT (coa Pa 4 in 1 CARTON	ckage Description	Size	nt Code Marketing Start Date	14mm Marketing End
Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 281-49	yellow SQUARE MINT (coa Pa 4 in 1 CARTON 10 in 1 BLISTE	ckage Description	Size	nt Code Marketing Start Date	14mm Marketing End
Color Shape Flavor Contains P - kaging # Item Code 1 NDC:68016- 281-49 1	yellow SQUARE MINT (coa Pa 4 in 1 CARTON 10 in 1 BLISTE Product	ckage Description R PACK; Type 0: Not a Con	Size	nt Code Marketing Start Date	14mm Marketing End
Color Shape Flavor Contains PCKaging # Item Code 1 NDC:68016- 281-49 1 1 NDC:68016- 281-49	yellow SQUARE MINT (coa 4 in 1 CARTON 10 in 1 BLISTE Product	ckage Description R PACK; Type 0: Not a Com ion	Size Impri	nt Code Marketing Start Date	14mm Marketing End
Color Shape Flavor Contains ///////////////////////////////////	yellow SQUARE MINT (coa 4 in 1 CARTON 10 in 1 BLISTE Product	ckage Description R PACK; Type 0: Not a Con ion tion Number or Mono Citation	Size Impri	nt Code Marketing Start Date 06/01/2013 Marketing Start	14mm Marketing End Date Marketing End

NICOTINE POLACRILEX COATED MINT

nicotine polacrilex gum, chewing

NICOTINE (UNII: 6M3C892Y6R) (NICOTINE - UNII:6M3C892Y6R) NICOTINE 4 mg Inactive Ingredients Ingredient Name Strength ACACIA (UNII: 5C5403N260) ACESULFAME POTASSUU (UNII: 230V73Q5G9) CARNAUBA WAX (UNII: R12CBM0EIZ) DAC YELLOW NO. 10 (UNII: 3355W5USQ3G) HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9X28H6N6OH) MAGNESIUM OXIDE (UNII: 333UGI71G) SODIUM BLARBONATE (UNII: 45P3261C7T) TALC (UNII: 75EV7]4R1U) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) XYLITOL (UNII: 15FIX9V2JP) XYLITOL (UNII: 75EV7]4R1U) FTALC (UNII: 75EV7]4R1U) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) XYLITOL (UNII: 15FIX9V2JP) XYLITOL (UNII: 75EV7]4R1U) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) XYLITOL (UNII: 15FIX9V2JP) XYLITO	Draduct Infe						
Route of Administration BUCCAL Active Ingredient/Active Molety Ingredient Name Basis of Strength Strength NICOTINE (UNII: 6M3C892 Y6R) (NICOTINE - UNII:6M3C892 Y6R) NICOTINE 4 mg Ingredient Name Strength Ingredient Name Strength ACACIA (UNII: 56/5403N260) Strength ACACIA (UNII: 52/5403N260) Strength CARNAUBA WAX (UNII: 812GBM0EIZ) Strength CARNAUBA WAX (UNII: 812GBM0EIZ) Strength MAGNESUMO XOL (UNII: 35X/9/2603) Strength ACACIA (UNII: 52/7/2603) Strength Sopulm CARBONATE (UNII: 45P3261C7T) Sopulm CARBONATE (UNII: 45P3261C7T) TALC (UNII: SEV7/4R1U) Inscore Sopulation CARBONATE (UNII: 45P3261C7T) Inscore Sopulation CARBONATE (UNII: 45P3261C7T) Inscore Sopulation Carbonation Sopulation Carbonation Product Characteristics <th< td=""><td>Product Info</td><td>rmation</td><td></td><td></td><td></td><td></td><td></td></th<>	Product Info	rmation					
Active Ingredient/Active Moiety Ingredient Name Ingredient Name Ingredient Name Ingredient Name Ingredient Name Ingredient Name IngredientS IngredientS IngredientS IngredientName IngredientS IngredientS IngredientName IngredientS IngredientS IngredientName IngredientS IngredientS IngredientS IngredientS IngredientS IngredientName IngredientS Ingred	Product Type		HUMAN OTC DRUG	Item Code	(Source)	NDC:6	8016-285
Ingredient Name Basis of Strength Strength IIICOTINE (UNII: 6M3C89ZY6R) NICOTINE 4 mg nactive Ingredients Ingredient Name Strength ractive Ingredients Ingredient Name Strength CACIA (UNII: 5C5403N260) Strength Strength CACIA (UNII: 5C5403N260) Strength Strength CACIA (UNII: 5C5403N260) Strength Strength CACIA (UNII: 525403N260) Strength Strength CACIA (UNII: 525403N260) Strength Strength AgRIESIUM (UNII: 8126M0EIZ) Strength Strength Soc YELLOW NO. 10 (UNII: 3200G1716) Strength Strength Strength Strength OXIBE (UNII: 3420G1716) Strength Strength Strength III (UNII: Stringvz]p) Strength Strength Strength III (UNII: 15FIX9vz]p) III (UNII: Strength) Strength Strength III (UNII: 15FIX9vz]p) III (III (IIII: 15FIX9vz]p) III (IIII (IIII: 15FIX9vz]p) Strength III (Coated mint) Imprint Code III (IIIIIIIIII (IIIIIIIIII) Strength III (IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	Route of Admin	istration	BUCCAL				
Ingredient Name Basis of Strength Strength NICOTINE (UNII: 6M3C89ZY6R) NICOTINE 4 mg Inactive Ingredients Ingredient Name Strength CACIA (UNII: 5C5403N260) Strength Strength CACIA (UNII: 525403N260) Strength Strength CACIA (UNII: 525403N260) Strength Strength SARNAUBA WAX (UNII: R12CBM0EIZ) Strength Strength SARNAUBA WAX (UNII: 812GBM0EIZ) Strength Strength Solut Strength (UNII: 3200G1716) Strength Strength Strength Strength (UNII: 3200G1716) Strength Strength Strength UNII: Strixsvzjp) Strength Strength Strength (UNII: Strixsvzjp) Introl (UNII: Strixsvzjp) Strength Strength Start Strength Strength Product Characteristics Strength Introl (UNII: Strixsvzjp) Strength Start Strength Introl (UNII: Strixsvzjp) Strength Start Strength Introl (UNII: Strixsvzjp) Strength Start Strength Introl (UNII: Strixsvzjp) Stre							
NICOTINE (UNII: 6M3C892Y6R) (NICOTINE - UNII: 6M3C892Y6R) NICOTINE 4 mg Inactive Ingredients Ingredient Name Ingredient Ingredient Ingredient Name Ingredient Name Ingredient	Active Ingred	ient/Active	Moiety				
Inactive Ingredients Ingredient Name Strength ACACIA (UNII: 5C5403N260) ACESULFAME POTASSIUM (UNII: 230V73Q5G9) CARNAUBA WAX (UMII: R12CEMOEIZ) ACESULFAME POTASSIUM (UNII: 323V73Q5G9) CARNAUBA WAX (UMII: R12CEMOEIZ) ACESULFAME POTASSIUM (UNII: 323V73Q5G9) CARNAUBA WAX (UMII: R12CEMOEIZ) ACESULFAME POTASSIUM (UNII: 8230V73Q5G9) CARNAUBA WAX (UMII: R12GEMOEIZ) ACESULFAME POTASSIUM (UNII: 835W5USQ3G) HYDRXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9X28H6N6OH) MAGNESIUM OXIDE (UNII: 3A3UGC1710) SODIUM CARBONATE (UNII: 4SP361C7T) TALC (UNII: 75EV7J4R1U) TTTANIUM DIOXIDE (UNII: 4SP362C17T) TALC (UNII: 75EV7J4R1U) TTTANIUM DIOXIDE (UNII: 15FIX9V2JP) KYLITOL (UNII: 75EV7J4R1U) TTTALC (UNII: 75EV7J4R1U) TTALC (UNII: 75EV7J4		Ingred	ient Name		Basis of Stre	ength	Strength
Ingredient Name Strength ACACIA (UNII: SC5403N260) CARNAUBA WAX (UNII: 230V73Q5G9) CARNAUBA WAX (UNII: 230V73Q5G9) CARNAUBA WAX (UNII: 355W5USQ3G) SC2 VELLOW NO. 10 (UNII: 355W5USQ3G) VELCELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N60H) MAGRESIUM OXIDE (UNII: 355W5USQ3G) SODIUM CARBONATE (UNII: 355W5U3QQ0) SODIUM CARBONATE (UNII: 357W5U3QQ0) SODIUM CARBONATE (UNII: 35FX9V2JP) TALC (UNII: 75EV7J4R1U) TTALU (UNII: 75EV7J4R1U) TTALC (UNII: 15F1X9V2JP) SOUARE SOUARE South Code Marketing Start Date <	NICOTINE (UNII: 61	M3C89ZY6R) (NI	COTINE - UNII:6M3C89ZY6F	{)	NICOTINE		4 mg
ACACIA (UNII: SC5403N260) ACACEJUFAME POTASSIUM (UNII: 230V73Q5G9) CARNAUBA WAX (UNII: R12CBMOBIZ) DGC YELLOW NO. 10 (UNII: 35SW5USQ3G) HYDROXYPROPYL CELLULOSE, UMSPECIFIED (UNII: 9XZBH6N6OH) MAGNESIUM OXIDE (UNII: 3AJU0GI71G) SODIUM BICARBONATE (UNII: MMPF3V39Q0) SODIUM CARBONATE (UNII: MMPF3V39Q0) SODIUM CARBONATE (UNII: SFIX9V3P0) SODIUM CARBONATE (UNII: STIX9V3P0) SODIUM CA	Inactive Ingre	edients					
ACCESULFAME POTASSIUM (UNII: 230V730569) 500 500 500 500 500 500 500 500 500 50			Ingredient Name				Strength
CARNAUBA WAX (UNII: R12CBM0EIZ) Image: Carnauba Wax (UNII: R12CBM0EIZ) Image: Carnauba Wax (UNII: R12CBM0EIZ) DAGC YELLOW NO. 10 (UNII: 355W5USQ3G) Image: Carnauba Wax (UNII: R12CBM0EIZ) Image: Carnauba Wax (UNII: R12CBM0EIZ) MAGNESIUM OXIDE (UNII: 3A3U0GI71G) Sodium CARBONATE (UNII: RM0F5V39Q0) Image: Carnauba Wax (UNII: R12FX892G1C7T) Sodium CARBONATE (UNII: R15FX9V2JP) Image: Carnauba Wax (UNII: R15FX9V2JP) Image: Carnauba Wax (UNII: R15FX9V2JP) Yittol (UNII: SFV7J4R1U) Image: Carnauba Wax (UNII: R15FX9V2JP) Image: Carnauba Wax (UNII: R15FX9V2JP) Yerduct Characteristics Score no score Shape SQUARE Size 14mm Flavor MINT (coated mint) Imprint Code Image: Carnauba Wax (UNII: R12CBM2 WAX (R12)) Packaging Image: Carnauba Wax (R12) 09/01/2013 Image: Carnauba Wax (R12) Yer Image: Carnauba Wax (R12) 09/01/2013 Image: Carnauba Wax (R12) Image: Carnauba Wax (R12) Yer Image: Carnauba Wax (R12) I			2201/220500				
bec YELLOW NO. 10 (UNII: 355W5USQ3G) HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9X28H6N6OH) MAGNESIUM OXIDE (UNII: 3AU0G171G) SODIUM BICARBONATE (UNII: 8MDF5V39QO) SODIUM CARBONATE (UNII: 8MDF5V39QO) SODIUM CARBONATE (UNII: 8MDF5V39QO) SODIUM CARBONATE (UNII: 15FiX9V2JP) KYLITOL (UNII: 75EV7J4RU) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) KYLITOL (UNII: 75EV7J4RU) KYLITOL (UNII: 7							
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9X28H6N60H) Image: Constant of the state of							
MAGNESIUM OXIDE (UNII: 3A3U0G171G) SODIUM BICARBONATE (UNII: 8MDF5V39QO) SODIUM CARBONATE (UNII: 8MDF5V39QO) SODIUM CARBONATE (UNII: 85P3261C7T) TALC (UNII: 75EV7J4R1U) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) XYLITOL (UNII: VCQ006KQ1E) Product Characteristics Color yellow Score no score Shape SQUARE Size 14mm FIavor MINT (coated mint) Imprint Code FIavor MINT (coated mint) Imprint Code Contains 9 Product Characteristics FIAVOR MINT (coated mint) 09/01/2013 1 NDC:68016- 1 NDC:68016- 1 NDC:68016- 1 NDC:68016- 1 0 in 1 CARTON 09/01/2013 1 NDC:68016- 1 0 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 1 NDC:68016- 2							
Solium BicARBONATE (UNII: 3MDF5V39QO) Solium CARBONATE (UNII: 45P3261C7T) TALC (UNII: 75EV7J4R1U) TTANIUM DIOXIDE (UNII: 15F1X9V2JP) XXLITOL (UNII: VCQ006KQ1E) Product Characteristics SQUARE MINT (coated mint) Imprint Code Marketing Start Marketing Start NDC:68016- 10 in 1 BLISTER PACK; Type 0: Not a Combin=100 SPACE SUB				(HUOMIOF			
Sodium CARBONATE (UNII: 45P3261C7T) Image: Constant of the stant of the sta							
TALC (UNII: 75EV7J4R1U) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) XYLITOL (UNII: VCQ006KQ1E) Product Characteristics Color yellow Score no score Shape SQUARE Size 14mm Flavor MINT (coated mint) MINT (coated mint) Contains MINT (coated mint) MINT (coated mint) MINT (coated mint) Proceed MINT (coated mint) MINT (co							
TITANIUM DIOXIDE (UNII: 15FiX9V2JP) Image: Constant of the second of	SODIOM CARBON		2010/1)				
WRITTOL (UNII: VCQ006KQ1E) Product Characteristics Soure no score SQUARE Size 14mm SQUARE Size 14mm Flavor MINT (coated mint) Imprint Code Contains MINT (coated mint) Marketing Start Marketing End Date Marketing Code Package Description Marketing Start Date Marketing End Date ID in 1 CARTON 09/01/2013 ID in 1 CARTON 09/01/2013 ID in 1 DISTER PACK; Type 0: Not a Combination Product Marketing Information Marketing Start Date Marketing Start Date Marketing End Date	TALC (LINUL 75 EV/7	1/10111)					
Product Characteristics Score no score SQUARE Size 14mm Flavor MINT (coated mint) Imprint Code Contains MINT (coated mint) Marketing Start Marketing Start Marketing End Date Package Description Marketing Start Marketing End Date NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 I NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 I NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 I NDC:68016- 285-44 10 in 1 ELISTER PACK; Type 0: Not a Combination Og/01/2013 I Ioi in 1 BLISTER PACK; Type 0: Not a Combination Product Marketing End Date Marketing Start Marketing End Date			(JIC)				
Color yellow Score no score Shape SQUARE Size 14mm Flavor MINT (coated mint) Imprint Code Contains MINT (coated mint) Imprint Code V Mint (coated mint) Marketing Start Date Marketing End Date NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 Marketing End Date NDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing Start Date Marketing End Date	TITANIUM DIOXID	E (UNII: 15FIX9V	′2JP)				
Color yellow Score no score Shape SQUARE Size 14mm Flavor MINT (coated mint) Imprint Code 14mm Contains MINT (coated mint) Imprint Code 14mm Kaging MINT (coated mint) Marketing Start Date Marketing End Date MDC:68016- 285-44 10 in 1 CARTON 09/01/2013 Marketing End Date MDC:68016- 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 09/01/2013 Imprint Code Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	TITANIUM DIOXID	E (UNII: 15FIX9V	(2JP)				
Shape SQUARE Size 14mm Flavor MINT (coated mint) Imprint Code 14mm Contains MINT (coated mint) Imprint Code 14mm Packaging MINT (coated mint) Marketing Start Date Marketing End Date # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 09/01/2013 1 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 09/01/2013 10 in 1 BLISTER PACK; Type 0: Not a Combination Product	TITANIUM DIOXID	E (UNII: 15FIX9V	'2JP)				
MINT (coated mint) Imprint Code Package Description Marketing Start Marketing End Date 1 NDC:68016- 285-44 10 in 1 CARTON 1 10 in 1 CARTON 10 10 in 1 BLISTER PACK; Type 0: Not a Combination Product Marketing Start Marketing End Date Marketing Category Application Number or Monograph Citation	TITANIUM DIOXID XYLITOL (UNII: VCC	9 E (UNII: 15FIX9V Q006KQ1E)	'2JP)				
Image: Second S	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char	E (UNII: 15FIX9V Q006KQ1E) acteristics	'2JP)	Score		no s	score
Image: Second S	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color	E (UNII: 15FIX9V Q006KQ1E) acteristics yellow	'2JP)				
# Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 09/01/2013 1 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 10 in 1 BLISTER PACK; Type 0: Not a Combination 10 in 1 BLISTER PACK; Type 0: Not a Combination Harketing Information Marketing Start Date Marketing Start Date Marketing End Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape	acteristics yellow SQUARE		Size	Code		
# Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 09/01/2013 1 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 10 in 1 BLISTER PACK; Type 0: Not a Combination 10 in 1 BLISTER PACK; Type 0: Not a Combination Harketing Information Marketing Start Date Marketing Start Date Marketing End Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor	acteristics yellow SQUARE		Size	Code		
# Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 09/01/2013 1 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 10 in 1 BLISTER PACK; Type 0: Not a Combination 10 in 1 BLISTER PACK; Type 0: Not a Combination Marketing Information Marketing Start Date Marketing Start Date Marketing End Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor	acteristics yellow SQUARE		Size	Code		
# Item Code Package Description Date Date 1 NDC:68016- 285-44 10 in 1 CARTON 09/01/2013 09/01/2013 1 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 10 in 1 BLISTER PACK; Type 0: Not a Combination 10 in 1 BLISTER PACK; Type 0: Not a Combination Marketing Information Marketing Start Marketing End Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains	acteristics yellow SQUARE		Size	Code		
1 285-44 10 in 1 BLISTER PACK; Type 0: Not a Combination 1 10 in 1 BLISTER PACK; Type 0: Not a Combination Product Product	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains Packaging	PE (UNII: 15FIX9V Q006KQ1E) Acteristics yellow SQUARE MINT (coat	ted mint)	Size Imprint C		14n	ım
Product Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains Packaging # Item Code	PE (UNII: 15FIX9V Q006KQ1E) Acteristics yellow SQUARE MINT (coat	ted mint)	Size Imprint C	arketing Start	14n	hm keting End
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains Packaging # Item Code	e (UNII: 15FIX9V Q006KQ1E) acteristics yellow SQUARE MINT (coal Pa 10 in 1 CARTOI	ted mint) ckage Description	Size Imprint C Ma	arketing Start Date	14n	hm keting End
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 285-44	e (UNII: 15FIX9V Q006KQ1E) acteristics yellow SQUARE MINT (coat 10 in 1 CARTOI 10 in 1 BLISTE	ted mint) ckage Description	Size Imprint C Ma	arketing Start Date	14n	hm keting End
Category Citation Date Date	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 285-44	e (UNII: 15FIX9V Q006KQ1E) acteristics yellow SQUARE MINT (coat 10 in 1 CARTOI 10 in 1 BLISTE	ted mint) ckage Description	Size Imprint C Ma	arketing Start Date	14n	hm keting End
	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 285-44	e (UNII: 15FIX9V Q006KQ1E) acteristics yellow SQUARE MINT (coat MINT (coat 10 in 1 CARTOI 10 in 1 BLISTE Product	ted mint) ckage Description N R PACK; Type 0: Not a Com	Size Imprint C Ma	arketing Start Date	14n	hm keting End
	TITANIUM DIOXID XYLITOL (UNII: VCC Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 285-44 1 1 Marketing Marketing	e (UNII: 15FIX9V Q006KQ1E) acteristics yellow SQUARE MINT (coat 10 in 1 CARTOI 10 in 1 BLISTE Product	ted mint) ckage Description N R PACK; Type 0: Not a Com ion tion Number or Monog	Size Imprint C 09/0 bination	arketing Start Date 1/2013	Marl	keting End

Product Info	rmation					
Product Type		HUMAN OTC DRUG	Item Co	ode (Source)	NDC:6	8016-560
Route of Admin	istration	BUCCAL				
Active Ingred	lient/Active	Moiety				
	Ingred	ient Name		Basis of Str	ength	Strength
NICOTINE (UNII: 6	M3C89ZY6R) (NI	COTINE - UNII:6M3C89ZY6R)		NICOTINE		4 mg
Inactive Ingre	edients					
		Ingredient Name				Strength
ACACIA (UNII: 5C5	403N26O)					
ACESULFAME PO		230V73Q5G9)				
	(UNII: R12CBM0E	IZ)				
D&C YELLOW NO	. 10 (UNII: 355V	V5USQ3G)				
HYDROXYPROPYL	CELLULOSE,	JNSPECIFIED (UNII: 9XZ8H	6N6OH)			
MAGNESIUM OXI	DE (UNII: 3A3U00	GI71G)				
SODIUM BICARBO	DNATE (UNII: 8M	IDF5V39QO)				
SODIUM CARBON	ATE (UNII: 45P3	261C7T)				
TALC (UNII: 7SEV7)	J4R1U)					
TITANIUM DIOXID	E (UNII: 15FIX9V	(2JP)				
XYLITOL (UNII: VC	Q006KQ1E)					
Product Char	acteristics					
			Score	3	no s	score
Color	yellow			3	no s 14m	
Color Shape	yellow SQUARE	ted mint)	Size	-		
Color Shape Flavor	yellow	ted mint)	Size	e nt Code		
Color Shape Flavor	yellow SQUARE	ted mint)	Size	-		
Color Shape Flavor Contains	yellow SQUARE	ted mint)	Size	nt Code	14m	ım
Color Shape Flavor Contains Packaging	yellow SQUARE MINT (coat	ted mint) ckage Description	Size	-	14m	ım
Color Shape Flavor Contains Packaging # Item Code	yellow SQUARE MINT (coat		Size Impri	nt Code Marketing Start	14m	nm keting End
1 NDC:68016-	yellow SQUARE MINT (coar Pa 2 in 1 CARTON		Size Impri	nt Code Marketing Start Date	14m	nm keting End
Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 560-00	yellow SQUARE MINT (coar 2 in 1 CARTON 10 in 1 BLISTE	ckage Description	Size Impri	nt Code Marketing Start Date	14m	nm keting End
Color Shape Flavor Contains EXAMPS Schemen Sc	yellow SQUARE MINT (coar 2 in 1 CARTON 10 in 1 BLISTE Product	ckage Description R PACK; Type 0: Not a Comb	Size Impri	nt Code Marketing Start Date	14m	nm keting End
Color Shape Flavor Contains Packaging # Item Code 1 NDC:68016- 560-00	yellow SQUARE MINT (coar 2 in 1 CARTON 10 in 1 BLISTE Product	ckage Description R PACK; Type 0: Not a Comb	Size Impri	nt Code Marketing Start Date	14m	nm keting End

	ex gum, chew	ing				
Product Info	rmation					
Product Type		HUMAN OTC DRUG	ltem Coc	le (Source)	NDC:6	8016-559
Route of Admir	istration	BUCCAL				
Active Ingred	liant/Activa	Maiaty				
Active ingred		ient Name		Basis of Str	onath	Strength
NICOTINE (UNII: 6		COTINE - UNII:6M3C89ZY6F	R)	NICOTINE	engti	2 mg
Inactive Ingra	edients					
J		Ingredient Name				Strength
ACACIA (UNII: 5C5	403N26O)	-				
ACESULFAME PO	TASSIUM (UNII:	230V73Q5G9)				
CARNAUBA WAX	(UNII: R12CBM0E	IZ)				
		JNSPECIFIED (UNII: 9XZ8H	16N6OH)			
MAGNESIUM OXI						
SODIUM BICARBO						
SODIUM CARBON		261C7T)				
TALC (UNII: 7SEV7						
TITANIUM DIOXIE XYLITOL (UNII: VC		2JP)				
	QUUUKQIE)					
Product Char	acteristics					
Color	white		Score		no s	score
	SQUARE		Size		14m	
						101
Shape	MINT (COa	ed mint)	Imprint	t Code		1111
Shape Flavor		ed mint)	Imprint	t Code		
Shape Flavor Contains		ed mint)	Imprint	t Code		
Shape Flavor Contains Packaging		ckage Description		t Code Marketing Start Date	Mar	
Shape Flavor Contains Packaging # Item Code				Marketing Start	Marl	keting End
Shape Flavor Contains Packaging # Item Code	Pa 2 in 1 CARTON		10	Marketing Start Date	Mar	keting End
Shape Flavor Contains Packaging Item Code NDC:68016- 559-00	Pa 2 in 1 CARTON 10 in 1 BLISTE Product	ckage Description R PACK; Type 0: Not a Com	10	Marketing Start Date	Mar	keting End
Shape Flavor Contains Peckaging # Item Code 1 NDC:68016- 559-00	Pa 2 in 1 CARTON 10 in 1 BLISTE Product	ckage Description R PACK; Type 0: Not a Com	bination 10	Marketing Start Date		keting End

Category	Citation	Date	Date
ANDA	ANDA078699	10/01/2014	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 10/2022

Chain Drug Consortium, LLC