RUGBY NICOTINE POLACRILEX GUM, ORIGINAL FLAVOR- nicotine polacrilex gum, chewing Rugby Laboratories, Inc.

Nicotine Polacrilex Gum 2 mg and 4 mg Original Flavor - Rugby

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 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.

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
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- 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 11 mg
- store at 20 25°C (68 77°F)
- protect from light

Other information - 4 mg

- each piece contains: calcium 110 mg, sodium 11 mg
- store at 20 25°C (68 77°F)
- protect from light

Inactive ingredients - 2 mg

acesulfame potassium, butylated hydroxytoluene, carnauba wax, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc.

Inactive ingredients - 4 mg

acesulfame potassium, butylated hydroxytoluene, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc.

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 Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

Stop Smoking Aid

2 mg Uncoated Original Flavor

Sugar-Free

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

If you smoke your first cigarette $\underline{\text{WITHIN}}$ 30 MINUTES of waking up, use Nicotine Polacrilex Gum USP, 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 verified

*This product is not manufactured or distributed by Haleon group of companies, distributor of Nicorette® Gum.

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

Distributed by:

RUGBY LABORATORIES

Indianapolis, IN 46268

Package label 2 mg

Drug Faate	Drug Fasta (continued)	R NDC 0536-3029-06	
Drug Facts Active ingredient (in each chewing piece) Purpose Nicoline polacritex2 mg (nicotine)Stop smoking aid Use "reduces withdrawal symptoms, including nicotine craving, associated with Text of the symptome of the sy	Drug Facts (continued) a do not eat or dink 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	BUC 0536-3029-06 Compare to the active ingredient in Nicorette [®] Gum [®]	the sale to those out of sales to those out of sales of control to sale in vending and the vertified annot ha vertified annot ha vertified annot have vertif
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.	use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hickups, heartfurm, nausea or other side effects. If 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. Lak to your hearth care provider.	Nicotine Gum Nicotine Polacrilex Gum USP, 2 mg (Nicotine)	
Ask a datofic fefore use if you have III a actium-restricted diet III heart dieses, neent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. III high blood pressure not controlled with medication. Nicotine can increase blood pressure. III stomach uider or diabetes III highor of equiptes	Other information each piece contains: calcium 115 mg, sodium 11 mg store at 20 - 25°C (88 - 77°) up rotect from light Inactive ingredients acesultame potassium, butylated hydroxytouene, carauba wax, flavors, gum base, sodium biachorate: sodium carbonale sonibut, haic	Stop Smoking Aid	The second secon
Ask a doctor or pharmacist before use II you are u using a non-nicotine stop smoking drug u taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.	Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST	2 mg	Pash provided in the contract of Model
Stop use and ask a doctor if m mouth, teeth, or jew problems occur in regular heartbeat or palpitations occur in ought symptoms of incorine overdoes such as nausea, vomiting, dizziness, diarrhae, weakness, and rapid heartbeat in you have symptoms of an allergic reaction (such as difficulty breathing or rash) Keep out of reach of children and pets. Pieces of nicoline gum may have enough nicoline to make children and pets. Pieces of nicoline gum may have enough throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center 1-00-022-1222.	*This product is not manufactured or distributed by Haleon group of companies, distributor of Nicorette [®] Gum.	Uncoated Original Flavor Sugar-Free	The second secon
Control Vertinet (1+00/-2/2-12/2/) right arrays: Directions If you are under 19 years of age, ask a doctor before use III from are under 19 years of age, ask a doctor before use III from the product, read the enclosed User's Guide for complete directions and other important information III grous smoke your first cigarette within 30 minutes of waking up, use 4 mg nicitie guide guide for the following 12 wakes schedule: 2 mg nicitie guide guide for a significant of the following 12 wakes schedule:		Actual Size FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP	ATORIES 16268 naceuticals.com
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 the with gum slowly until it tingles. Then park it between your cheek and gum. When the tingle results W repeat this process until most of the tingle is gone flow. the tingle is gone.	See inside for more details or visit www.nixthehabit.com	If you smoke your first cigarette <u>WITHIN</u> 30 MINUTES of waking up, use Nicotine Polacrilex Gum USP, 4 mg 50 Pieces, 2 mg EACH	Distributed by: Rucaby LABORATORIES Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.
		PLD-C6198 FC000976 Rev. 01/24 R-58 Re-order No. 370102 3 05363 02906 1 5	

RUGBY Nicotine Gum Uncoated Original Flavor

Lot No.: Exp. Date:

Principal display panel 4 mg

Compare to the active ingredient in Nicorette® Gum*

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid

4 mg

Uncoated Original Flavor

Sugar-Free

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

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 Haleon group of companies distributor of Nicorette® Gum.

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

Distributed by:

RUGBY® LABORATORIES

Indianapolis, IN 46268

Package label 4 mg

Drug Facts	Drug Facts (continued)	Rugby [®] NDC 0536-3030-06	
Active ingredient (in each chewing piece) Purpose Nicotine polacrilex4 mg (nicotine)	 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 	Compare to the active ingredient in Nicorette® Gum*	a set to those a value to those of age required as of thm any where proof of not be writing and any of the original and original and or
 reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking 	 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 		and f number 1 proor number 1 machin source age car age car vour p vour p vour p vour p
Warnings If you are program to 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 safe than smoking. However, the risks to your child from this medicine are not fully known.	eause 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.	Nicotine Gum Nicotine Polacrilex Gum USP, 4 mg (Nicotine)	
Ask a doctor before use if you have a sodium-restricted diet iherd tossesse, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. Injh blood pressure not controlled with medication. Nicotine can increase blood	Other information weach piece contains: calcium 110 mg, sodium 11 mg work store at 20 - 25°C (68 - 77F) work from light	Stop Smoking Aid	k Gum per day x Gum per day User's Guide.
pressure. ■ stomach ulcer or diabetes ■ listory of seizures Ask a doctor or pharmacist before use If you are	Inactive ingredients acesultame potassium, butylated hydroxytoluene, camauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavys, gum base, sodium bicarbonate, sodium	1 mg	the endoced like the second of
using a non-nicotine stop smoking drug taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.	carbonate, sorbition (see southin losse, southin losse) carbonate, sorbition, talc Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST	4 mg	Phase of No.
Stop use and ask a doctor if munth, tesh r, oisy problems occur in regular heartbeat or paintaisions occur in you get symptoms of incotine overdose such as nausea, vomiting, dizziness, diarriba, vedankness, and rapid heartbeat	"This product is not manufactured or distributed by Haleon group of companies, distributor of Nicorette [®] Gum.	Uncoated Original Flavor Sugar-Free	Event of the second secon
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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 bedin using the union your guid day		Poliuli Jug	
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Weeks 1 to 6 Weeks 7 to 9 Weeks 1 to 12 1 piece every 1 piece every 1 piece every 1 to 2 hours 2 to 4 hours 4 to 8 hours minotifne gum is a medicine and must be used a certain way to get the best 10 to 2 hours		If you smoke your first cigarette <u>MORE</u> <u>THAN</u> 30 MINUTES after waking up, use Nicotine Polacrilex Gum USP, 2 mg	Distributed by: BugBy* LaboRatORIES Indiamolis, IN 4268 (800) 616-2471 www.majorpharmaceuticals.
■ including guint is a mean-mean mice to be used a definition with the used and the second and		50 Pieces, 4 mg EACH	Distribut RUGBY* Indianap (8000) 616 Www.ma
	See inside for more details or visit www.nixthehabit.com		
		PLD-C6258 FC008979 Rev. 01/24 R-58 Re-order No. 370107	
		3 05363 "03006 " 1	

RUGBY Nicotine Gum Uncoated Original Flavor

Lot No.: Exp. Date:

RUGBY NICOTINE POLACRILEX GUM, ORIGINAL FLAVOR

nicotine polacrilex gum, chewing

Product Information					
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC:05	36-3029
Route of Administration	BUCCAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Stre	ngth	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NIC	COTINE - UNII:6M3C89ZY6R)	NICOTINE		2 mg
Inactive Ingredients					
	Ingredient Name			S	trength

ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white (off-white to tan)	Score	no score
Shape	SQUARE	Size	14mm
Flavor		Imprint Code	
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536- 3029-23	11 in 1 CARTON	03/15/1999	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536- 3029-34	2 in 1 CARTON	03/15/1999	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0536- 3029-06	5 in 1 CARTON	03/15/1999	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
M	larketing	Information		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
AN	DA	ANDA074507	03/15/1999	

RUGBY NICOTINE POLACRILEX GUM, ORIGINAL FLAVOR

nicotine polacrilex gum, chewing

Product Information					
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC:05	36-3030
Route of Administration	BUCCAL				
Active Ingredient/Active	Moiety				
Ingredient Name Basis of Strength Strength				Strength	

NICOTINE

Inactive Ingr	edients			
j.	Ingredient N	lame		Strength
ACESULFAME PO	TASSIUM (UNII: 230V73Q5G9)			Strength
	ROXYTOLUENE (UNII: 1P9D0Z171	K)		
	(UNII: R12CBM0EIZ)	,		
	D. 10 (UNII: 35SW5USQ3G)			
	2 (UNII: L06K8R7DQK)			
	0 (UNII: WZ B9127XOA)			
	IO. 6 (UNII: H77VEI93A8)			
SODIUM BICARB	ONATE (UNII: 8MDF5V39QO)			
SODIUM CARBON	NATE (UNII: 45P3261C7T)			
SORBITOL (UNII:	506T60A25R)			
TALC (UNII: 7SEV7	′J4R1U)			
Product Cha	racteristics			
Color	yellow (yellowish)	Score	1	no score
Shape	SQUARE	Size		14mm
Flavor		Imprir	nt Code	
Contains				
Packaging				
# Item Code	Package Descrip	tion	Marketing Start	Marketing End
	i uckuge beschip		Date	Date
1 NDC:0536- 3030-23	11 in 1 CARTON		03/19/1999	
	10 in 1 BLISTER PACK; Type 0: No	ot a Combination		
1	Product			
2 NDC:0536-	5 in 1 CARTON		03/19/1999	
3030-06		at a Combination		
2 10 in 1 BLISTER PACK; Type 0: Not a Combination Product				
Marketing	Information			
-		. M	Manlas the Olivia	Maximit = 1
Marketing Marketing Category	Application Number or	Monograph	Marketing Start Date	Marketing End Date
-		[.] Monograph	Marketing Start Date 03/19/1999	Marketing End Date

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 3/2024

Rugby Laboratories, Inc.