

NICOTINE- nicotine polacrilex gum, chewing
Dr. Reddy's Laboratories Inc.

Nicotine Polacrilex Gum Coated Ice Mint 4 mg ANDA204833 - Equate

Drug Facts

Active ingredient (in each chewing piece)

Nicotine Polacrilex (equal to 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

- **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 to 2 hours	1 piece every 2 to 4 hours	1 piece every 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

- **each piece contains:** calcium 115 mg, sodium 8 mg

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

Inactive ingredients

acacia, acesulfame potassium, carnauba wax, D&C yellow #10, FD&C blue #2, FD&C red #40, FD&C yellow #6, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide, xylitol.

Questions or comments?

Call toll-free **1-800-585-8682** weekdays (8:00am - 8:00 pm EST)

Principal Display Panel

*Compare to the active ingredient in Nicorette® Gum

Habitrol

Nicotine Polacrilex Gum

USP, 4 mg (nicotine)

STOP SMOKING AID

Gum

4mg

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 Habitrol gum, 2 mg Gum

Sugar Free coated nicotine gum

COATED FRUIT FLAVOR

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivate 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

To remove the gum, tear off single unit

Peel off backing starting at corner with loose edge

Push gum through foil

- 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:

Dr. Reddy's Laboratories, Inc.

Princeton, NJ 08540

Package Label

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To remove the gun
tear off single unit.



Peel off backing starting at corner with loose edge



Push gum through
foil.

*Compare to the active ingredient in Nicorette® Gum

150
PIECES
4 mg EACH



STOP SMOKING AID



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1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677, 2678, 26

Invasive ingrederent

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repeated with events and as well the event was done in a different order.

do not use more than 24 pieces a day

■ If you experience itching or discomfort changing, you may use a second piece.

[illegible]

150
PIECES
4 mg EACH

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

Sugar-free

6w + 7

STOP SMOKING AID

Coated
Fruit
Flavor

405 1174

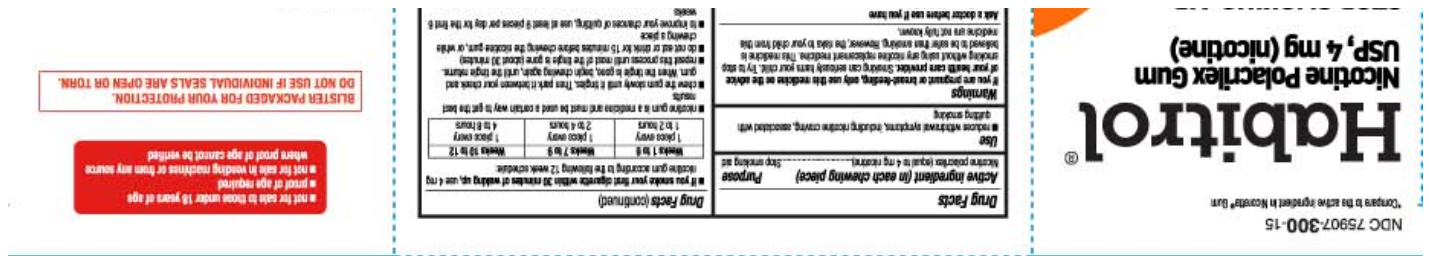
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06/2025

Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540

DISTRIBUTED BY:



HABITROL Nicotine Polacrilex Gum Coated Fruit Flavor

<div>NICOTINE</div> <div>nicotine polacrilex gum, chewing</div>			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75907-300
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
ACACIA (UNII: 5C5403N26O)			
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
SODIUM CARBONATE (UNII: 45P3261C7T)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
XYLITOL (UNII: VCQ006KQ1E)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
Product Characteristics			
Color	yellow (light tan)	Score	no score
Shape	SQUARE	Size	14mm
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75907-300-80	80 in 1 CARTON	06/12/2025	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:75907-300-15	150 in 1 CARTON	06/12/2025	
2		1 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
ANDA	ANDA079038	06/12/2025	

Labeler - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 6/2025

Dr. Reddy's Laboratories Inc.