Consumer Healthcare Products Association

Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975

July 28, 2014

	INGREDIENT	ADULT DOSAGE	PRODUCT CATEGORY	DATE OF OTC APPROVAL	PRODUCT EXAMPLES
1.	brompheniramine maleate	4 mg/4-6 hours (oral)	antihistamine	September 9, 1976	Dimetapp
2.	chlorpheniramine maleate	4 mg/4-6 hours (oral)	antihistamine	September 9, 1976	Chlor-Trimeton, Coridicin HBP, Triaminic Cold & Allergy
3.	oxmetazoline hydrochloride	0.05% aqueous solution (topical)	nasal decongestant	September 9, 1976	Afrin, Neo-Synephrine-12 Hour
4.	pseudoephedrine hydrochloride	60 mg/4 or 4-6 hours (oral) 240 mg max./24 hours	nasal decongestant	September 9, 1976	Sudafed
5.	pseudoephedrine sulfate	60 mg/4 or 4-6 hours (oral)	nasal decongestant	September 9, 1976	Drixoral
6.	xylometazoline hydrochloride	0.01% aqueous solution (topical)	nasal decongestant	September 9, 1976	Natru-Vent
7.	doxylamine succinate (NDA)	25 mg single dose only (oral)	sleep-aid	October 18, 1978	Unisom
8.	hydrocortisone	0.25 to 0.50% (topical)	antipruritic (anti-itch)	December 4, 1979+	Cortaid, Lanacort
9.	hydrocortisone acetate	0.25 to 0.50% (topical)	antipruritic (anti-itch)	December 4, 1979+	Bactine
10.	acidulated phosphate fluoride rinse	0.02% fluoride in aqueous solution	dental rinse	March 28, 1980	
11.	sodium fluoride rinse	0.05% aqueous solution (topical)	dental rinse	March 28, 1980	Fluorigard
12.	stannous fluoride gel	0.4% gel (topical)	anticaries gel	March 28, 1980	GelKam Gel
13.	stannous fluoride rinse	0.1% aqueous solution (topical)	dental rinse	March 28, 1980	
14.	ephedrine sulfate	0.1 to 1.25% (topical)	anorectal/vasoconstrictor	May 27, 1980	Pazo Ointment
15.	epinephrine hydrochloride	0.005 to 0.01% (topical)	anorectal/vasoconstrictor	May 27, 1980	
16.	phenylephrine hydrochloride	0.25% (topical)	anorectal/vasoconstrictor	May 27, 1980	
17.	chlorpheniramine maleate (NDA)	12 mg/12 hours (oral timed-release)	antihistamine	July 23, 1981	Triaminic 12
18.	phenylpropanolamine hydrochloride (NDA)	75 mg/12 hours (oral timed-release)	nasal decongestant	July 23, 1981	
19.	diphenhydramine hydrochloride (NDA)	25 mg/4 hours (oral)	antitussive	August 7, 1981	Benylin
20.	haloprogin	1.0% (topical)	antifungal	March 23, 1982	
21.	miconazole nitrate	2.0% (topical)	antifungal	March 23, 1982	Micatin
22.	diphenhydramine hydrochloride	50 mg single dose only (oral)	sleep-aid	April 23, 1982	Sominex 2
23.	diphenhydramine monocitrate	76 mg single dose only (oral)	sleep-aid	April 23, 1982	Excedrin PM
24.	dyclonine hydrochloride	0.05 to 0.1% solution or suspension, 1 to 3 mg as lozenge	oral anesthetic	May 25, 1982	Sucrets Maximum Strength
25.	dexbrompheniramine maleate (NDA)	6 mg/12 hours (oral timed-release)	antihistamine	September 3, 1982	Drixoral
26.	pseudoephedrine sulfate (NDA)	120 mg/12 hours (oral timed-release)	nasal decongestant	September 3, 1982	Afrinol Repetabs
27.	triprolidine hydrochloride	2.5 mg/4-6 hours	antihistamine	November 26, 1982	Actifed Capsules
28.	ibuprofen (NDA)	200 mg/4-6 hours (oral)	internal analgesic/ antipyretic	May 18, 1984	Advil, Nuprin
29.	dexbrompheniramine maleate	2 mg/4-6 hours (oral)	antihistamine	January 15, 1985	
30.	diphenhydramine hydrochloride	25-50 mg/4-6 hours (oral)	antihistamine	January 15, 1985	Benadryl

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31.	pseudoephedrine hydrochloride(NDA)	120 mg/12 hours (oral timed-release)	nasal decongestant	June 17, 1985	Actifed
32.	triprolidine hydrochloride (NDA)	5 mg/12 hours	antihistamine	June 17, 1985	Actifed 12-hour Capsules
33.	oxymetazoline hydrochloride (NDA)	0.025% solution/drops (topical)	occular vasoconstrictor	May 30, 1986	Ocuclear
34.	pyrantel pamoate	11 mg/kg of body weight maximum dose 1 g (oral)	anthelmintic	August 1, 1986	Pin-X
35.	povidone iodine sponge (NDA)	10% (new dosage form)	antimicrobial	January 7, 1987	E-Z Scrub 241
36.	diphenhydramine hydrochloride	25-50 mg/4-6 hours (oral)	antiemetic	April 30, 1987	
37.	dexbrompheniramine maleate (NDA)	3 mg/6-8 hours (oral)	antihistamine	May 22, 1987	Drixoral Plus
38.	chlophedianol hydrochloride	25 mg/6-8 hours (oral)	antitussive	August 12, 1987	
39.	doxylamine succinate	7.5 mg - 12.5 mg./4-6 hours (oral)	antihistamine	August 24, 1987	Nyquil
40.	loperamide (NDA)	4 mg, then 2 mg, 8 mg/day (oral)	antidiarrheal	March 3, 1988	Imodium A-D (Johnson & Johnson)
41.	hydrogenated soybean oil and lecithin	12.4 g powder in 2-3 oz water 20 minutes before gall bladder x-rays	cholecystokinetic	February 28, 1989	Liposperse (Merck)
42.	ibuprofen, pseudoephedrine HCl (NDA)*	200 mg ibuprofen, 30 mg pseudoephedrine HCl	analgesic/decongestant	September 19, 1989	Advil Cold and Sinus (Wyeth)
43.	clotrimazole (NDA)	1% lotion and cream/2 times daily	antifungal	October 23, 1989	Lotrimin AF (Schering)
44.	permethrin (NDA)	1% cream rinse	pediculicide (head lice)	May 5, 1990	Nix (Warner-Lambert)
45.	clotrimazole (NDA)	1% cream & 100 mg inserts	anticandidal	November 30, 1990	Gyne-Lotrimin (Schering), Mycelex-7 (Miles)
46.	miconazole nitrate	2.0% cream and 100 mg inserts	anticandidal	March 13, 1991	Monistat 7 (Ortho)
47.	hydrocortisone+	Above 0.50% to 1.0%	antipruritic (anti-itch)	August 30, 1991	
48.	hydrocortisone acetate+	Above 0.50% to 1.0%	antipruritic (anti-itch)	August 30, 1991	
49.	clemastine fumarate (NDA)	1.34 mg/12 hours	antihistamine	August 21, 1992	Tavist-1 (Novartis)
50.	clemastine fumarate (in combination with phenylpropanolamine HCl (NDA)	1.34 mg/12 hours	antihistamine/ decongestant	August 21, 1992	Tavist-D (Novartis)
51.	dexchlorpheniramine maleate	2 mg/4-6 hours (oral)	antihistamine	December 9, 1992	(last monograph switch)
52.	naproxen sodium (NDA)	220 mg/4-6 hours (oral)	internal analgesic/ antipyretic	January 11, 1994	Aleve (Bayer)
53.	pheniramine maleate with naphazoline HCl (NDA)	0.3%; 0.025% in solution	ophthalmic antihistamine/ decongestant	June 8, 1994	Naphcon A (Alcon), Opcon A (Bausch & Lomb) Ocuhist (Akorn)
54.	antazoline phosphate with naphazoline HCl (NDA)	0.5%; 0.05% in solution	ophthalmic antihistamine/ decongestant	July 11, 1994	Vasocon A (Ciba)
55.	famotidine (NDA)	10 mg, up to 20 mg/day	acid reducer	April 28, 1995	Pepcid AC (J&J·Merck)
56.	ibuprofen suspension 100mg/5ml for pediatric use (NDA)	7.5 mg/kg up to 4 times a day	internal analgesic/ antipyretic	June 16, 1995	Children's Motrin (McNeil Consumer)
57.	cimetidine (NDA)	200 mg up to twice per day	acid reducer	June 19, 1995	Tagamet HB (GlaxoSmithKline)
58.	ketoprofen (NDA)	12.5 mg every 4 to 6 hours	internal analgesic	October 6, 1995	Orudis KT (Wyeth), Actron (Bayer)
59.	ranitidine (NDA)	75 mg up to twice per day	acid reducer	December 19, 1995	Zantac 75 (McNeil)
60.	butoconazole nitrate (NDA)	2.0% cream and applicators (3 days)	anticandidal	December 26, 1995	Femstat 3 (Procter & Gamble)

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61.	minoxidil (NDA)	2.0% topical solution	hair grower	February 9, 1996	Rogaine (McNeil)
62.	nicotine polacrilex (NDA)	2 mg and 4 mg gum	smoking cessation	February 9, 1996	Nicorette (GlaxoSmithKline)
63.	nizatidine (NDA)	75 mg up to twice daily	acid reducer	May 9, 1996	AXID AR (Wyeth)
64.	miconazole nitrate (NDA)	2.0% cream and 200-mg inserts	anticandidal	April 16, 1996	Monistat 3 (Ortho)
65.	nicotine transdermal system (NDA)	15 mg. patch	smoking cessation	July 3, 1996	Nicotrol (McNeil Consumer)
66.	clotrimazole (NDA)*	1% cream & 200 mg inserts	anticandidal	July 29, 1996	Gyne-Lotrimin 3 (Schering-Plough)
67.	nicotine transdermal system (NDA)	21, 14, & 7 mg patch	smoking cessation	August 2, 1996	Nicoderm CQ (GlaxoSmithKline Beecham) Habitrol (Novartis) (Nov. 12, 1999)
68.	bentoquatam (NDA)*	5% lotion	poison ivy protection	August 26, 1996	Ivy Block (EnviroDerm)
69.	cromolyn sodium (NDA)	4% nasal solution	allergy prevention & treatment	January 6, 1997	Nasalcrom (McNeil Consumer)
90.	tioconazole (NDA)	6.5% vaginal ointment	anticandidal	February 11, 1997	Vagistat-1 (Bristol-Myers Squibb), Monistat 1 (McNeil)
71.	loperamide/simethicone (NDA)*	2 mg loperamide, 125 mg simethicone	antidiarrheal/antigas	June 26, 1997	Imodium Advanced (McNeil Consumer)
72.	triclosan (dentifrice) (NDA)*	0.30% triclosan/0.243% fluoride	antigingivitis	July 11, 1997	Total (Colgate-Palmolive)
73.	ketoconazole (NDA)	1% shampoo	dandruff shampoo	October 10, 1997	Nizoral (Johnson & Johnson Consumer Products)
74.	minoxidil (NDA)*	5.0% topical solution	hair grower	November 17, 1997	Rogaine Extra Strength for Men (Johnson & Johnson)
75.	aspirin /caffeine /acetaminophen(NDA)**	250 mg/65 mg/250 mg	migraine	January 14, 1998	Excedrin Migraine (Novartis)
76.	miconazole nitrate (NDA)*	4.0% cream	anticandidal	March 30, 1998	Monistat 3 (Advanced Care Products)
77.	terbinafine hydrochloride (NDA)	1.0% cream	antifungal	March 9, 1999	Lamisil AT (Novartis)
78.	cimetidine suspension (NDA)*	Suspension	acid reducer	July 9, 1999	Tagamet HB 200 (GlaxoSmithKline)
79.	naproxen Na, pseudoephedrine HCl (NDA)*	220 mg naproxen Na, 120 mg pseudoephedrine HCl	analgesic/decongestant	November 29, 1999	Aleve Cold & Sinus (Bayer Consumer Care)
80.	ibuprofen (NDA)**	200 mg	migraine	February 25, 2000	Motrin Migraine Pain (McNeil Consumer Healthcare)
81.	ibuprofen (NDA)**	200 mg	migraine	March 16, 2000	Advil Migraine Liqui-Gels (Wyeth)
82.	docosanol (NDA)*	10% cream	cold sore/fever blister	July 25, 2000	Abreva Cream (Avanir Pharmaceuticals)
83.	famotidine, calcium carbonate, magnesium hydroxide (NDA)*	10 mg famotidine, 800 mg calcium carbonate, 165 mg magnesium hydroxide	heartburn, acid indigestion	October 17, 2000	Pepcid Complete (J&J/Merck)
84.	butenafine hydrochloride (NDA)	1.0% cream	athlete's foot, jock itch, ringworm	December 7, 2001	Lotrimin Ultra (Schering-Plough)
85.	ibuprofen, pseudoephedrine HCl, suspension for pediatric use (NDA)*	100 mg ibuprofen, 15 mg pseudo-ephedrine HCl/5 ml; 5 or 10 ml up to 4 times a day	analgesic/decongestant	April 18, 2002	Children’s Advil Cold (Wyeth)
86.	guaifenesin extended-release tablet (NDA)	600 or 1200 mg once or twice a day	expectorant	July 12, 2002	Mucinex (Adams Respiratory Therapeutics)
87.	nicotine polacrilex troche/lozenge (NDA)*	2 mg and 4 mg	smoking cessation	October 31, 2002	Commit (GlaxoSmithKline)

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88.	loratadine (NDA)	10 mg/day	antihistamine	November 27, 2002	Claritin Tablets, Claritin RediTabs, Claritin Syrup (Schering-Plough)
89.	loratadine, pseudoephededrine sulfate (NDA)	10 mg loratadine, 240 mg pseudo-ephedrine sulfate Daily	antihistamine/ decongestant	November 27, 2002	Claritin-D 12 Hour Extended Release Tablets, Claritin-D 24 Hour Extended Release Tablets (Schering-Plough)
90.	omeprazole magnesium (NDA)	20 mg/day	acid reducer to treat frequent heartburn	June 20, 2003	Prilosec OTC (Procter & Gamble)
91.	loratadine (NDA)**	10 mg/day	hives relief	November 15, 2003	Claritin hives relief (Schering-Plough)
92.	diphenhydramine citrate & ibuprofen (NDA)*; diphenhydramine HCl & ibuprofen potassium (NDA)*	400 mg ibuprofen and 78 mg diphenhydramine citrate or 50 mg diphenhydramine HCl at bedtime	analgesic sleep-aid	December 21, 2005	Advil PM (Wyeth)
93.	ecamsule (combined with avobenzone and octocrylene (NDA)*	2% ecamsule; 2% avobenzone; 10% octocrylene	sunscreen	July 21, 2006	Anthelios SX (L'Oreal)
94.	levonorgestrel (NDA)	Two 0.75-mg tablets, with the second one taken 12 hours after the first	contraceptive	August 24, 2006	Plan B (Duramed)
95.	polyethylene glycol 3350 (NDA)	17 g (scoopful) of powder per day in 8 oz of water	laxative	October 6, 2006	MiraLAX (Schering-Plough)
96.	ketotifen (NDA)	0.025% ophthalmic solution	antihistamine eye drops	October 19, 2006	Zaditor (Novartis)
97.	orlistat (NDA)	60 mg; 180 mg daily max.	weight loss aid	February 7, 2007	alli (GlaxoSmithKline)
98.	cetirizine HCl & pseudoephedrine HCl (NDA)	5 mg cetirizine and 120 mg pseudoephedrine	antihistamine/ decongestant	November 9, 2007	Zyrtec-D (McNeil)
99.	cetirizine HCl (NDA)	1 mg/ml (children's syrup), 5 mg and 10 mg (tablets and chewable tablets)	antihistamine, hives relief	November 16, 2007	Zyrtec (McNeil)
100.	lansoprazole (NDA)	15 mg/day	acid reducer to treat frequent heartburn	May 18, 2009	Prevacid 24 HR (Novartis)
101.	levonorgestrel (NDA)	1.5 mg	contraceptive	July 10, 2009	Plan B One Step (Duramed)
102.	omeprazole and sodium bicarbonate (NDA)	20 mg omeprazole and 1100 mg sodium bicarbonate	acid reducer to treat frequent heartburn	December 1, 2009	Zegerid OTC (Schering-Plough)
103.	ibuprofen and phenylephrine HCl (NDA)	200 mg ibuprofen and 10 mg phenylephrine HCl	analgesic/decongestant	May 27, 2010	Advil Congestion Relief (Pfizer)
104.	fexofenadine hydrochloride (NDA)	30 mg; 60 mg; 180 mg 30 mg/5 mL	antihistamine	January 24, 2011	Allegra (Chattem)
105.	fexofenadine hydrochloride and pseudoephedrine HCl (NDA)	60 mg; 120 mg	antihistamine/ decongestant	January 24, 2011	Allegra D 12-Hour (Chattem)
106.	fexofenadine hydrochloride and pseudoephedrine HCl (NDA)	180 mg; 240 mg	antihistamine/ decongestant	January 24, 2011	Allegra D 24-Hour (Chattem)
107.	oxybutynin (NDA)	3.9 mg	overactive bladder	January 25, 2013	Oxytrol for Women (Merck)
108.	triamcinolone acetonide (NDA)	55 mcg/spray, aqueous suspension	intranasal steroid for allergic rhinitis	October 11, 2013	Nasacort Allergy 24HR (Chattem)
109.	esomeprazole magnesium (NDA)	20 mg/day	acid reducer to treat frequent heartburn	March 28, 2014	Nexium 24HR (Pfizer)
110.	fluticasone propionate (NDA)	50 mcg/spray	intranasal steroid for upper	July 23, 2014	Flonase Allergy Relief (GlaxoSmithKline)

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		respiratory allergies		

*+ FDA approval for OTC marketing is on an interim basis pending adoption of a Final Monograph. * New OTC NDA - Not previously Rx **New OTC indication, product previously OTC*