

Consumer Healthcare Products Association

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

January 26, 2006

	INGREDIENT	ADULT DOSAGE	PRODUCT CATEGORY	DATE OF OTC APPROVAL	PRODUCT EXAMPLES
1.	brompheniramine maleate	4 mg./4-6 hours (oral)	antihistamine	September 9, 1976	Dimetane (A.H. Robins)
2.	chlorpheniramine maleate	4 mg./4-6 hours (oral)	antihistamine	September 9, 1976	Allerest (Pharmacraft), Chlor-Trimeton (Schering), Contac (SmithKline), Sudafed Plus (Warner-Lambert)
3.	oxmetazoline hydrochloride	0.05% aqueous solution (topical)	nasal decongestant	September 9, 1976	Afrin (Schering), Duration (Plough), Dristan Long Lasting (Whitehall), Neo-Synephrine-12 Hour (Bayer)
4.	pseudoephedrine hydrochloride	60 mg./4 or 4-6 hours (oral) 240 mg. max./24 hours	nasal decongestant	September 9, 1976	Sudafed (Warner-Lambert), Neo-Synephrinol (Bayer)
5.	pseudoephedrine sulfate	60 mg./4 or 4-6 hours (oral)	nasal decongestant	September 9, 1976	Afrinol (Schering), Chlor-Trimeton (Schering)
6.	xylometazoline hydrochloride	.01% aqueous solution (topical)	nasal decongestant	September 9, 1976	Orrivin (Ciba)
7.	doxylamine succinate (NDA)	25 mg. single dose only (oral)	sleep-aid	October 18, 1978	Unisom (Pfizer)
8.	hydrocortisone	0.25 to 0.50% (topical)	antipruritic (anti-itch)	December 4, 1979+	Cortaid (Upjohn), Lanacort (Combe)
9.	hydrocortisone acetate	0.25 to 0.50% (topical)	antipruritic (anti-itch)	December 4, 1979+	Bactine (Miles), Caldecort (Pharmacraft)
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 (Colgate-Palmolive)
12.	stannous fluoride gel	0.4% gel (topical)	anticaries gel	March 28, 1980	GelKam Gel (Colgate-Palmolive)
13.	stannous fluoride rinse	0.1% aqueous solution (topical)	dental rinse	March 28, 1980	Stan Care (Block)
14.	ephedrine sulfate	0.1 to 1.25% (topical)	anorectal/vasoconstrictor	May 27, 1980	Pazo Ointment (Bristol-Myers)
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 (Sandoz)
18.	phenylpropanolamine hydro- chloride (NDA)	75 mg./12 hours (oral timed-release)	nasal decongestant	July 23, 1981	Triaminic 12 (Sandoz)
19.	diphenhydramine hydrochloride (NDA)	25 mg./4 hours (oral)	antitussive	August 7, 1981	Benylin (Parke-Davis)
20.	haloprogin	1.0% (topical)	antifungal	March 23, 1982	
21.	miconazole nitrate	2.0% (topical)	antifungal	March 23, 1982	Micatin (Ortho)
22.	diphenhydramine hydrochloride	50 mg. single dose only (oral)	sleep-aid	April 23, 1982	Sominex 2 (Beecham), Sleep-eze 3 (Whitehall)
23.	diphenhydramine monochlorate	76 mg. single dose only (oral)	sleep-aid	April 23, 1982	Excedrin PM (Bristol-Myers)
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 (SmithKline)
25.	dexbrompheniramine maleate (NDA)	6 mg./12 hours (oral timed-release)	antihistamine	September 3, 1982	Drixoral (Schering)
26.	pseudoephedrine sulfate (NDA)	120 mg./12 hours (oral timed-release)	nasal decongestant	September 3, 1982	Afrinol Repetabs (Schering)
27.	triprolidine hydrochloride	2.5 mg./4-6 hours	antihistamine	November 26, 1982	Actifed Capsules (Warner-Lambert), Actidil Syrup and Capsules (Warner-Lambert)
28.	ibuprofen (NDA)	200 mg./4-6 hours (oral)	internal analgesic/ antipyretic	May 18, 1984	Advil (Whitehall), Nuprin (Bristol-Myers)
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 25 (Warner-Lambert)

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31.	pseudoephedrine hydrochloride(NDA)	120 mg./12 hours (oral timed-release)	nasal decongestant	June 17, 1985	Actifed (Warner-Lambert)
32.	triprolidine hydrochloride (NDA)	5 mg./12 hours	antihistamine	June 17, 1985	Actifed 12-hour Capsules (Warner-Lambert)
33.	oxymetazoline hydrochloride (NDA)	0.025% solution/drops (topical)	ocular vasoconstrictor	May 30, 1986	Ocuclear (Schering)
34.	pyrantel pamoate	11 mg./kilo of body weight maximum dose 1 gram (oral)	anthelmintic	August 1, 1986	Pin-X (Efficon)
35.	povidone iodine sponge (NDA)	10% (new dosage form)	antimicrobial	January 7, 1987	E-Z Scrub 241 (Deseret)
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 (Schering)
38.	chlorthalidol 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 (Procter & Gamble)
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 gm. powder in 2-3 oz. Water 20 minutes before gall bladder x-rays	cholecystokinetic	February 28, 1989	Lipospense (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 (Sandoz Consumer)
50.	clemastine fumarate (in combination with phenylpropanolamine HCl (NDA)	1.34 mg./12 hours	antihistamine/ decongestant	August 21, 1992	Tavist-D (Sandoz Consumer)
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 (SmithKline)
58.	ketoprofen (NDA)	12.5 mg every 4 to 6 hours	internal analgesic	October 16, 1995	Orudis KT (Whitehall-Robins), Actron (Bayer)
59.	ranitidine (NDA)	75 mg up to twice per day	acid reducer	December 19, 1995	Zantac 75 (Warner Wellcome)
60.	butoconazole nitrate (NDA)	2.0% cream and applicators (3 days)	anticandidal	December 26, 1995	Femstat 3 (Procter & Gamble)
61.	minoxidil (NDA)	2.0% topical solution	hair grower	February 9, 1996	Rogaine (Pharmacia & Upjohn)

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62.	nicotine polacrilex (NDA)	2 mg and 4 mg gum	smoking cessation	February 9, 1996	Nicorette (SmithKline Beecham)
63.	nizatidine (NDA)	75 mg up to twice daily	acid reducer	May 9, 1996	AXID AR (Whitehall-Robins Healthcare)
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 (SmithKline 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	Nasal crom (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 (Pharmacia & Upjohn)
75.	aspirin /caffeine /acetaminophen(NDA)**	250mg/65mg/250mg	migraine	January 14, 1998	Excedrin Migraine (Bristol-Myers Squibb)
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 (SmithKline Beecham)
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 (Whitehall-Robins)
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.	nicotine polacrilex troche/lozenge (NDA)*	2 mg and 4 mg	smoking cessation	October 31, 2002	Commit (GlaxoSmithKline)
87.	loratadine (NDA)	10 mg/day	antihistamine	November 27, 2002	Claritin Tablets, Claritin RediTabs, Claritin Syrup (Schering-Plough)

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88.	loratadine, pseudoephedrine 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)
89.	omeprazole magnesium	20 mg/day	acid reducer to treat frequent heartburn	June 20, 2003	Prilosec OTC (Procter & Gamble)
90.	loratadine (NDA)	10 mg/day	hives relief	November 15, 2003	Claritin hives relief (Schering-Plough)

*+ 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*