

New Antimicrobial Agents Approved by the U.S. Food and Drug Administration in 1999 and New Indications for Previously Approved Agents

Date of approval	Trade name (form)	Generic name(s)	Manufacturer	Indications or use
5 Jan 99	Lamisil (emulsion, cream)	Terbinafine hydrochloride	Novartis Pharmaceuticals Corp.	Expansion of labeling to include patients with onychomycosis of fingernail or toenail even when associated with nondermatophytes
5 Jan 99	Meproon (suspension)	Atovaquone	Glaxo Wellcome Inc.	For prevention of <i>Pneumocystis carinii</i> pneumonia
22 Jan 99	Prevpac (tablet)	Amoxicillin, clarithromycin, lansoprazole	Tap Holdings Inc.	For eradication of <i>Helicobacter pylori</i> to reduce the risk of duodenal ulcer recurrence
9 Mar 99	Lamisil (emulsion, cream)	Terbinafine hydrochloride	Novartis Pharmaceuticals Corp.	For over-the-counter treatment of tinea pedis (athlete's foot), tinea cruris (jock itch), and tinea corporis (ringworm) due to <i>Epidermophyton floccosum</i> , <i>Trichophyton mentagrophytes</i> , and <i>Trichophyton rubrum</i>
30 Mar 99	Sporanox (injectable)	Itraconazole	Janssen Research, Johnson and Johnson	For treatment of blastomycosis, histoplasmosis and aspergillosis in immunocompromised and nonimmunocompromised patients
15 Apr 99	Agenerase (capsule)	Amprenavir	Glaxo Wellcome Inc.	For use in children age 4 and older and in adults in combination with other antiretrovirals for HIV infection
26 May 99	Norvir (capsule, solution)	Ritonavir	Abbott Laboratories	For treatment of HIV infection in combination with other antiretroviral agents
29 Jun 99	Norvir (capsule, soft gelatin)	Ritonavir	Abbott Laboratories	For treatment of HIV infection in combination with other antiretroviral agents
30 Jun 99	Monistat dual pak (suppository)	Miconazole nitrate	Advanced Care Products	Treatment of vulvovaginal candidiasis
1 Jul 99	Videx (tablets, powder for oral solution)	Didanosine	Bristol-Myers Squibb Co.	Expansion of the monotherapy indication to provide for use in combination with other antiretroviral agents for treatment of HIV-1 infection
1 Jul 99	Zerit (capsules, oral solution)	Stavudine	Bristol-Myers Squibb Co.	Expansion of the monotherapy indication to provide for use in combination with other antiretroviral agents for treatment of HIV-1 infection
14 Jul 99	Omnicef (powder for oral suspension)	Cefdinir	Parke Davis, Warner-Lambert Co.	For a 5-day dosing regiment (7 mg/kg twice daily) for treatment of acute otitis media
26 Jul 99	Relenza (inhalant)	Zanamivir	Glaxo Wellcome Inc.	For treatment of uncomplicated acute illness due to influenza virus in adults and adolescents 12 years and older who have been symptomatic for no more than 2 days
26 Jul 99	Lamisil (gel)	Terbinafine	Novartis Pharmaceuticals Corp.	For treatment of tinea cruris
13 Aug 99	Cleocin (suppository)	Clindamycin phosphate	Pharmacia and Upjohn Co.	For treatment of bacterial vaginosis

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24 Aug 99	Ceftin (tablet)	Cefuroxime axetil	Glaxo Wellcome Inc.	For treatment of acute bacterial maxillary sinusitis in pediatric patents
21 Sep 99	Synercid (injectable)	Dalfopristin, quinupristin	Rhone Poulenc Rorer Pharmaceuticals Inc.	For treatment of complicated skin and skin structure infections and for treatment of vancomycin-resistant <i>Enterococcus faecium</i>
27 Oct 99	Tamiflu (capsule)	Oseltamivir phosphate	Hoffmann-La Roche Inc.	For treatment of uncomplicated acute illness due to influenza infections in adults who have been symptomatic for no more than 2 days
28 Oct 99	Videx (tablet, powder for oral solution)	Didanosine	Bristol-Myers Squibb Co.	For a new strength as well as allowing a change in dosing interval to once-daily administration in combination therapy for treatment of HIV-1 infection
8 Nov 99	Omnicef (capsule)	Cefdinir	Parke Davis, Warner-Lambert Co.	For a 5-day dosing regimen (300 mg twice daily) for treatment of acute exacerbations of chronic bronchitis
24 Nov 99	Viracept (tablet, powder)	Nelfinavir mesylate	Agouron Pharmaceuticals Inc.	For a 1,250-mg twice-daily dosing regimen in combination with other antiretroviral therapies as an alternative to the standard dosing regimen of 750 mg three times daily in combination with other antiretrovirals for treatment of HIV infection
10 Dec 99	Avelox (tablet)	Moxifloxacin hydrochloride	Bayer Corporation	For acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, community-acquired pneumonia, and uncomplicated skin and skin structure infections
17 Dec 99	Tequin (tablet; injectable)	Gatifloxacin	Bristol-Myers Squibb	For community-acquired pneumonia; acute bacterial exacerbation of chronic bronchitis; acute sinusitis; uncomplicated skin and skin structure infections; uncomplicated urinary tract infections; complicated urinary tract infections; pyelonephritis; uncomplicated urethral, pharyngeal, and rectal gonorrhea in males; and endocervical, pharyngeal, and rectal gonorrhea in females
17 Dec 99	Penlac (solution)	Ciclopirox	Hoechst Marion Roussel Inc.	For topical treatment in immunocompetent patients with mild to moderate <i>Trichophyton rubrum</i> onychomycosis of fingernails and toenails without lunula involvement