

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 |

Continued on following page

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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 |