

Medication Guides

The following information is provided by the FDA's Center for Drug Evaluation and Research. Hyperlinks to the medication guides are provided on the following website: www.fda.gov/cder/Offices/ODS/medication_guides.htm.

FDA may require distribution of Medication Guides, FDA-approved patient information, for selected prescription drugs that pose a serious and significant public health concern. Medication Guides will be required if the FDA determines that one or more of the following circumstances exist:

- patient labeling could help prevent serious adverse effects
- the drug product has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product
- the drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness

Medication Guides are available for these products:

LISTED BY DRUG NAME

**biologic or drug/biologic combination*

- Accutane (2005 version) also marketed under the following generic names:
 - Amnesteem
 - Claravis
 - Sotret
- Actiq (2006 version)
- Advair Diskus (2006 version)
- Advair HFA 230/21 Inhalation Aerosol (2006 version)
- *Avonex (2003 version)
- Brovana (2006 version)
- Copegus (page 30 of the label) (2001 version)
- Cordarone (2005 version)
- Coumadin (2006 version)
- Elidel Cream (2006 version)
- Emsam (2006 version)
- Epzicom (page 17 of the label) (2004 version)
- Exubera (2006 version)
- Fentora (2006 version)
- Foradil Aerolizer (2006 version)
- Forteo (page 18 of the label) (2004 version)
- *Infergen (2002 versions)
- Lariam (2003 version)
- Lindane Lotion (2003 version)
- Lindane Shampoo (2003 version)
- Lotronex (page 14 of the label) (2006 version)
- Mifepristone (Mifeprex) (2005 version)
- Nolvadex (page 31 of the label) (2004 version)
- Palladone (2004 version)
- *Pegasys (page 34 of the label) (2005 version)
- *PEG-Intron
- Protopic Ointment (2006 version)
- Rebetal (page 30 of the label) (2001 version)
- *Rebif (2002 version)
- *Rebetron (page 36 of the label) (2001 version)
- Remicade (2006 version)
- Revlimid
- Ribasphere (page 30 of the label) (2001 version)

- Ribavirin (2001 version)
- *Roferon-A prefilled syringes (2003 version)
- *Roferon-A solution for injection (2003 version)
- Serevent Diskus (2006 version)
- Soltamox
- Soriatane (2004 version)
- Stratterra (2005 version)
- Symbicort (2006 version)
- Symmlin (page 20 of the label) (2005 version)
- Tracleer (page 18 of the label) (2005 version)
- Trizivir (page 22 of the label) (2005 version)
- Tyasabri (2006 version)
- Viramune (page 22 of the label) (2005 version)
- Xyrem (page 25 of the label) (2005 version)
- Ziagen (Page 17 of the label) (2000 version)

LISTED BY ACTIVE INGREDIENT

**biologic or drug/biologic combination*

- abacavir sulfate and lamivudine (Epzicom) (page 17 of the label) (2004 version)
- abacavir sulfate (Ziagen) (page 17 of the label) (2000 version)
- abacavir sulfate, lamivudine, and zidovudine combination (Trizivir) (page 22 of the label) (2005 version)
- acitretin (Soriatane) (page 3 of the label) (2004 version)
- alosetron hydrochloride (Lotronex) (page 14 of the label) (2006 version)
- amiodarone (Cordarone) (2005 version)
- Antidepressants in Children and Teenagers (Template) (1/26/2005)
- o Anti-Depressants with Medication Guides for Pediatric Suicidality (8/2/2005)
- arformoterol tartrate (Brovana) (2006 version)
- atomoxetine hydrochloride (Strattera) (2005 version)
- bosentan (Tracleer) (page 18 of the label) (2005 version)
- budesonide and formoterol (Symbicort) (2006 version)
- fluticasone propionate and salmeterol (Advair HFA) (2006 version)
- fentanyl buccal tablet (Fentora) (2006 version)
- fentanyl citrate (Actiq) (2006 version)
- formoterol fumarate (Foradil Aerolizer) (2006 version)
- hydromorphone hydrochloride (Palladone) (2004 version)
- infliximab (Remicade) (2006 version)
- *interferon alpha-2a, recombinant (Roferon-A) (2003 version)
 - solution for injection, prefilled syringes
 - solution for injection, vials
- *interferon beta-1a (Rebif) (2002 version)
- *interferon alfacon-1 (Infergen) (2002 versions)
- *interferon beta-1a (Avonex) or (2003 version)
- isotretinoin (Accutane, Amnesteem, Claravis, Sotret) (2005 version)
- insulin human [rDNA origin] (Exubera) (2006 version)
- lenolidamide (Revlimid)
- Lindane Lotion (2003 version)
- Lindane Shampoo (2003 version)
- mefloquine hydrochloride (Lariam) (2003 version)
- mifepristone (Mifeprex) (2005 version)
- nevirapine (Viramune) (page 22 of the label) (2005 version)
- natalizumab (Tysabri) (2006 version)
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Template (6/15/2005)
- *peginterferon alfa-2a (Pegasys) (page 34 of the label)
- *peginterferon alfa 2b (PEG-Intron) (2005 version)
- pimecrolimus (Elidel Cream) (2006 version)
- pramlintide acetate (Symmlin) (page 20 of the label) (2005 version)
- ribavirin (Rebetol, Ribasphere, Ribavirin Copegus) (page 30 of the label) (2001 version)
- *ribavirin and interferon alfa-2b combination (Rebetron) (page 36 of the label) (2001 version)
- salmeterol xinafoate (Serevent Diskus) (2006 version)
- salmeterol xinafoate/fluticasone propionate (Advair Diskus) (2006 version)
- selegiline transdermal system (Emsam) (2006 version)
- sodium oxybate (Xyrem) (2005 version)
- tacrolimus (Protopic Ointment) (2006 version)
- tamoxifen (Nolvadex) (page 31 of the label) (2004 version)
- tamoxifen citrate (Soltamox)
- teriparatide (rDNA origin) (Forteo) (page 19 of the label) (2004 version)
- warfarin (Coumadin) 2006 version