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***Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER) -- January 2007***

The detailed view includes drug products with safety labeling changes to the **BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE** sections. Deletions or editorial revisions made to these sections are not included in this summary.

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<b>Brand (Generic) Name</b>	<b>Sections Modified</b>	<b>Summary of Changes to Contraindications and Warnings</b>
Tasmar (tolcapone) Tablets  Prescribing Information	<p><b>BOXED WARNING</b></p> <p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Information for Patients                             <ul style="list-style-type: none"> <li>◦ Tasmar should not be used by patients until there has been a complete discussion.....</li> </ul> </li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• .....As of May 2005, 3 cases of fatal fulminant hepatic failure have been reported from more than 40,000 patient years.....</li> </ul> <p><b>PATIENT ACKNOWLEDGEMENT OF RISKS ASSOCIATED WITH TASMAR TREATMENT</b></p>	<p>Above <b>BOXED WARNING</b> Section</p> <p>Tasmar should not be used by patients until there has been a complete discussion of the risks and the patient has provided written acknowledgement that the risks have been explained.....</p> <p><b>BOXED WARNING</b></p> <p>As of May 2005, 3 cases of fatal fulminant hepatic failure have been reported from more than 40,000 patient years of worldwide use.</p> <p>Tasmar should be discontinued if SGPT/ALT or SGOT/AST levels exceed 2 times the upper limit of normal or if clinical signs and symptoms.....</p>

<p>Toradol (ketorolac tromethamine tablets)</p> <p>Prescribing Information</p> <p>Medication Guide</p>	<p><b>BOXED WARNING</b></p> <ul style="list-style-type: none"> <li>• Gastrointestinal Effects</li> <li>• Cardiovascular Risk</li> </ul> <p><b>CONTRAINDICATIONS</b></p> <p><b>WARNINGS</b></p> <ul style="list-style-type: none"> <li>• Gastrointestinal Effects - Risk of Ulceration, Bleeding, and Perforation</li> <li>• Anaphylactoid Reactions</li> <li>• Cardiovascular Effects                         <ul style="list-style-type: none"> <li>○ Cardiovascular Thrombotic Events</li> <li>○ Hypertension</li> </ul> </li> <li>• Congestive Heart Failure and Edema</li> <li>• Skin Reactions</li> </ul> <p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• General                         <ul style="list-style-type: none"> <li>○ Hepatic Effect</li> <li>○ Hematologic Effect</li> </ul> </li> <li>• Preexisting Asthma</li> <li>• Information for Patients</li> <li>• Laboratory Tests</li> <li>• Drug Interactions                         <ul style="list-style-type: none"> <li>○ Aspirin</li> <li>○ Diuretics</li> <li>○ Lithium</li> <li>○ Methotrexate</li> <li>○ ACE Inhibitors</li> <li>○ Pentoxifylline</li> <li>○ Nondepolarizing Muscle Relaxants</li> </ul> </li> <li>• Pregnancy                         <ul style="list-style-type: none"> <li>○ Teratogenic Effects</li> <li>○ Nonteratogenic Effects</li> </ul> </li> </ul> <p><b>MEDICATION GUIDE (new)</b></p>	<p>See highlighted prescribing information for revised text.</p>
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Brand (Generic)	Sections Modified	Summary of Changes to
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Name		Contraindications and Warnings
<p>Sustiva (efavirenz) Capsules and Tablets</p> <p>Prescribing Information</p> <p>Patient Package Insert</p>	<p><b>CONTRAINDICATIONS</b></p> <p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Drug Interactions                             <ul style="list-style-type: none"> <li>◦ Table 5                                     <ul style="list-style-type: none"> <li>▪ Antifungal   <ul style="list-style-type: none"> <li>▪ Voriconazole</li> </ul> </li> <li>▪ Calicum Channel Blocker   <ul style="list-style-type: none"> <li>▪ Bepridil</li> </ul> </li> <li>▪ Neuroleptic   <ul style="list-style-type: none"> <li>▪ Pimozide</li> </ul> </li> </ul> </li> <li>◦ Table 6                                     <ul style="list-style-type: none"> <li>▪ Antifungals   <ul style="list-style-type: none"> <li>▪ Itraconazole</li> <li>▪ Ketoconazole</li> </ul> </li> <li>▪ Antimycobacterial   <ul style="list-style-type: none"> <li>▪ Rifampin</li> </ul> </li> <li>▪ Calcium Channel Blockers   <ul style="list-style-type: none"> <li>▪ Diltiazem</li> <li>▪ Others.....</li> </ul> </li> </ul> </li> </ul> </li> </ul> <p><b>PATIENT PACKAGE INSERT</b></p> <ul style="list-style-type: none"> <li>• Medicines You Should Not Take With Sustiva.....</li> <li>• The following medicines may need to be replaced with another medicine.....</li> <li>• The following medicines may require a change in the dose of Sustiva or the other medicine.</li> </ul>	<p><b>CONTRAINDICATIONS</b></p> <p>Sustiva should not be administered concurrently with astemizole, bepridil, cisapride, midazolam, pimozide, triazolam, or ergot derivatives because competition for CYP3A4 by efavirenz could result in inhibition of metabolism of these drugs and create the potential for serious and/or life-threatening adverse events (eg, cardiac arrhythmias, prolonged sedation, or respiratory depression). Sustiva should not be administered concurrently with standard doses of voriconazole because Sustiva significantly decreases voriconazole plasma concentrations. Adjusted doses of voriconazole and efavirenz may be administered concomitantly.....</p>

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Brand (Generic) Name	Sections Modified	Summary of Changes to Contraindications and Warnings
<p>Minocin (minocycline for injection) Intravenous</p>	<p><b>WARNINGS</b></p> <p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Information for Patients                             <ul style="list-style-type: none"> <li>◦ Diarrhea is a common</li> </ul> </li> </ul>	<p><b>WARNINGS</b></p> <p>Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all</p>

<p>Prescribing Information</p>	<p>problem caused by antibiotics.....</p>	<p>antibacterial agents, including Minocin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of <i>C. difficile</i>.....</p>
<p>Minocin (minocycline hydrochloride) Oral Suspension</p> <p>Prescribing Information</p>	<p><b>WARNINGS</b></p> <p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Information for Patients             <ul style="list-style-type: none"> <li>◦ Diarrhea is a common problem caused by antibiotics.....</li> </ul> </li> </ul>	<p><b>WARNINGS</b></p> <p>Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Minocin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of <i>C. difficile</i>.....</p>
<p>Mobic (meloxicam) Tablets and Oral Suspension</p> <p>Prescribing Information</p>	<p><b>WARNINGS</b></p> <ul style="list-style-type: none"> <li>• Renal Effects</li> </ul> <p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Information for Patients             <ul style="list-style-type: none"> <li>◦ In late pregnancy, as with other NSAIDs, Mobic (meloxicam) tablets/oral suspension should be avoided because it may cause premature closure of the ductus arteriosus.</li> </ul> </li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Adult             <ul style="list-style-type: none"> <li>◦ Osteoarthritis and Rheumatoid Arthritis                 <ul style="list-style-type: none"> <li>▪ Table 3                     <ul style="list-style-type: none"> <li>■ Body as a Whole                             <ul style="list-style-type: none"> <li>■ Accident Household</li> </ul> </li> </ul> </li> </ul> </li> </ul> </li> <li>• Pediatrics</li> </ul>	<p><b>WARNINGS: Renal Effects</b></p> <p>Long-term administration of NSAIDs, including Mobic (meloxicam) tablets/oral suspension, can result in renal papillary necrosis, renal insufficiency, acute renal failure, and other renal injury.</p> <p>.....Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics, ACE inhibitors, and angiotensin II receptor antagonists, and the elderly.....</p>

	<ul style="list-style-type: none"> <li>○ Pauciarticular and Polyarticular Course Juvenile Rheumatoid Arthritis (JRA)             <ul style="list-style-type: none"> <li>■ Urinary System                 <ul style="list-style-type: none"> <li>■ Acute Urinary Retention</li> </ul> </li> </ul> </li> </ul>	
<p>Rapamune (sirolimus) Oral Solution and Tablets</p> <p>Prescribing Information</p>	<p><b>WARNINGS</b></p> <p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• De Novo Use Without Cyclosporine</li> <li>• Angioedema</li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• High-Risk Patients</li> </ul>	<p><b>WARNINGS</b></p> <p>.....Renal function should be closely monitored during the co-administration of Rapamune with cyclosporine because long-term administration of the combination has been associated with deterioration of renal function.....</p>
<p>Zevalin (ibritumomab tiuxetan)</p> <p>Prescribing Information</p>	<p><b>WARNINGS</b></p> <ul style="list-style-type: none"> <li>• Secondary Leukemia and Myelodysplastic Syndrome</li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Secondary Leukemia and Myelodysplastic Syndrome</li> </ul>	<p><b>WARNINGS: Secondary Leukemia and Myelodysplastic Syndrome</b></p> <p>Myelodysplastic syndrome (MDS) and/or acute myelogenous leukemia (AML) were reported in 5.2% (11/211) of patients enrolled in clinical studies and 1.5% (8/535) of patients included in the expanded-access trial, with median follow-up of 6.5 and 4.4 years, respectively. Among the 19 reported cases, the median time to the diagnosis of MDS or AML was 1.9 years following treatment with the Zevalin therapeutic regimen; however, the cumulative incidence continues to increase.</p>

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<p>Actimmune (interferon gamma-1b)</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• General             <ul style="list-style-type: none"> <li>◦ Isolated cases of acute serious hypersensitivity reactions have been observed in patients receiving Actimmune.....</li> </ul> </li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Actimmune has also been evaluated in additional disease states in studies in which patients have generally received higher doses (&gt;100 mcg/m<sup>2</sup>/three times weekly) administered by intramuscular or subcutaneous injection, or intravenous infusion.....</li> <li>• Immunological             <ul style="list-style-type: none"> <li>◦ Increased Autoantibodies</li> <li>◦ Lupus-like Syndrome</li> </ul> </li> <li>• Metabolic             <ul style="list-style-type: none"> <li>◦ Hypertriglyceridemia</li> </ul> </li> <li>• Other             <ul style="list-style-type: none"> <li>◦ Chest Discomfort</li> </ul> </li> </ul>
<p>Avandamet (rosiglitazone maleate and metformin hydrochloride) Tablets</p> <p>Prescribing Information</p> <p><a href="#">See MedWatch Safety Alert posted 2/20/2007</a> regarding rosiglitazone maleate clinical trial results which showed an increased incidence of fractures in female patients receiving long-term treatment with Avandia (rosiglitazone maleate).</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Rosiglitazone Maleate             <ul style="list-style-type: none"> <li>◦ Hypoglycemia</li> <li>◦ Weight Gain                 <ul style="list-style-type: none"> <li>■ Table 7</li> </ul> </li> </ul> </li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Initial Section</li> <li>• Table 8</li> <li>• Table 9</li> <li>• Combination with Insulin</li> </ul>
<p>Cialis (tadalafil) Tablets</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Drug Interactions             <ul style="list-style-type: none"> <li>◦ Effects of Other Drugs on Cialis                 <ul style="list-style-type: none"> <li>■ Cytochrome P450 Inhibitors                     <ul style="list-style-type: none"> <li>■ HIV Protease Inhibitor                         <ul style="list-style-type: none"> <li>■ Ritonavir</li> </ul> </li> </ul> </li> </ul> </li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Alpha Blockers             <ul style="list-style-type: none"> <li>■ Alfuzosin                 <ul style="list-style-type: none"> <li>■ Table 10</li> </ul> </li> </ul> </li> </ul>
<p>Desferal (deferoxamine mesylate injection, USP)</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Geriatric Use</li> </ul>
<p>Eloxatin (oxaliplatin) Powder, for Solution for Intravenous Use</p> <p>Prescribing Information</p>	<p><b>USE IN SPECIFIC POPULATIONS</b></p> <ul style="list-style-type: none"> <li>• Pediatric Use</li> </ul>
<p>Flomax (tamsulosin hydrochloride) Capsules</p> <p>Prescribing Information &amp; Patient Package Insert</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• General             <ul style="list-style-type: none"> <li>○ Intraoperative Floppy Iris Syndrome</li> </ul> </li> <li>• Information for Patients</li> </ul> <p><b>PATIENT PACKAGE INSERT</b></p> <ul style="list-style-type: none"> <li>• What you need to know while taking Flomax (tamsulosin hydrochloride) capsules             <ul style="list-style-type: none"> <li>○ If you are contemplating cataract surgery, make certain to advise your eye surgeon that you have taken Flomax capsules.</li> </ul> </li> </ul>
<p>Inderal LA (propranolol hydrochloride) Long-Acting Capsules</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Pregnancy: Pregnancy Category C             <ul style="list-style-type: none"> <li>○ .....Intrauterine growth retardation, small placentas, and congenital anomalies have been reported in neonates whose mothers received propranolol during pregnancy. Neonates whose mothers are receiving propranolol at parturition have exhibited bradycardia, hypoglycemia and/or respiratory depression.....</li> </ul> </li> </ul>

<p>Indocin (indomethacin) Capsules, Oral Suspension, and Suppositories</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Pediatric Use             <ul style="list-style-type: none"> <li>○ .....If indomethacin treatment is instituted, a suggested starting dose is 1-2 mg/kg/day given in divided doses.....</li> </ul> </li> </ul>
<p>Indocin I.V. (indomethacin for injection)</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Drug Interaction             <ul style="list-style-type: none"> <li>○ Indomethacin usually does not influence the hypoprothrombinemia produced by anticoagulants.....</li> <li>○ In some patients with compromised renal function, the co-administration of an NSAID and an ACE inhibitor or angiotensin II antagonist may result....</li> </ul> </li> </ul>
<p>Lipitor (atorvastatin calcium) Tablets</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Use in Patients with Recent Stroke or TIA</li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Postintroduction Reports             <ul style="list-style-type: none"> <li>○ Tendon Rupture</li> </ul> </li> </ul>
<p>NovoLog (insulin aspart [rDNA origin]) Injection</p> <p>Prescribing Information</p> <p>Patient Package Insert</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• General             <ul style="list-style-type: none"> <li>○ Pregnancy and Lactation</li> </ul> </li> <li>• Information for Patients             <ul style="list-style-type: none"> <li>○ For All Patients</li> </ul> </li> <li>• Pregnancy - Teratogenic Effects - Pregnancy Category B</li> </ul> <p><b>PATIENT PACKAGE INSERT</b></p> <ul style="list-style-type: none"> <li>• Who should not use NovoLog?</li> </ul>

<p>Progesterone Injection, USP in Sesame Oil for Intramuscular Use Only</p> <p>Prescribing Information</p> <p>Patient Package Insert</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Geriatric Use</li> <li>• Pediatric Use</li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Initial Section <ul style="list-style-type: none"> <li>○ Pain</li> <li>○ Irritation, and/or redness at the injection area</li> </ul> </li> </ul> <p><b>PATIENT PACKAGE INSERT (new)</b></p>
<p>Transderm Scōp (transdermal scopolamine) System</p> <p>For prescribing information, contact Novartis Consumer Health, Inc. at 1-800-452-0051.</p>	<p><b>PRECAUTIONS &amp; PATIENT PACKAGE INSERT</b></p> <ul style="list-style-type: none"> <li>• Skin burns have been reported at the patch site in several patients wearing an aluminized transdermal system during a magnetic resonance imaging scan (MRI). Because Transderm Scōp contains aluminum, it is recommended to remove the system before undergoing an MRI.</li> </ul>
<p>Wellbutrin (bupropion hydrochloride) Tablets</p> <p>Prescribing Information</p> <p>Medication Guide</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Renal Impairment</li> <li>• Information for Patients</li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Other Events Observed During the Development of Wellbutrin <ul style="list-style-type: none"> <li>○ Special Senses <ul style="list-style-type: none"> <li>■ Increased Intraocular Pressure</li> </ul> </li> </ul> </li> </ul> <p><b>MEDICATION GUIDE</b></p> <ul style="list-style-type: none"> <li>• Introductory Section</li> <li>• What is the most important information I should know about Wellbutrin? <ul style="list-style-type: none"> <li>○ What is important information I should know and share with my family about taking antidepressants?</li> <li>○ General Information about Wellbutrin.</li> </ul> </li> </ul>

<p>Wellbutrin SR (bupropion hydrochloride) Sustained-Release Tablets</p> <p>Prescribing Information</p> <p>Medication Guide</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• Renal Impairment</li> <li>• Information for Patients</li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Table 4             <ul style="list-style-type: none"> <li>◦ Special Senses                 <ul style="list-style-type: none"> <li>▪ Blurred Vision or Diplopia</li> </ul> </li> </ul> </li> <li>• Other Events Observed During the Clinical Development and Postmarketing Experience of Bupropion             <ul style="list-style-type: none"> <li>◦ Special Senses                 <ul style="list-style-type: none"> <li>▪ Increased Intraocular Pressure</li> </ul> </li> </ul> </li> </ul> <p><b>MEDICATION GUIDE</b></p> <ul style="list-style-type: none"> <li>• Introductory Section</li> <li>• What is the most important information I should know about Wellbutrin SR?             <ul style="list-style-type: none"> <li>◦ What is important information I should know and share with my family about taking antidepressants?</li> <li>◦ General information about Wellbutrin SR.</li> </ul> </li> </ul>
<p>Xenical (orlistat) Capsules</p> <p>Prescribing Information</p>	<p><b>PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>• General             <ul style="list-style-type: none"> <li>◦ Substantial weight loss can increase the risk of cholelithiasis.....</li> </ul> </li> </ul> <p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Other Clinical Studies or Postmarketing Surveillance             <ul style="list-style-type: none"> <li>◦ Pancreatitis has been reported with the use of Xenical in postmarketing surveillance.....</li> </ul> </li> </ul>

Brand (Generic) Name	Sections Modified
<p>Vidaza (azacitidine for injection) for Subcutaneous and Intravenous Use Only</p> <p>Prescribing Information</p>	<p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Most Commonly Occurring Adverse Reactions (SC or IV) <ul style="list-style-type: none"> <li>○ The most commonly adverse reaction by IV route also included petechiae, rigors, weakness and hypokalemia.</li> </ul> </li> <li>• Discussion of Adverse Reactions Information <ul style="list-style-type: none"> <li>○ Overall, adverse reaction were qualitatively similar between IV and SC studies.....</li> </ul> </li> </ul>
<p>Xifaxan (rifaximin) Tablets</p> <p>Prescribing Information</p>	<p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• Post-marketing Experience <ul style="list-style-type: none"> <li>○ Exfoliative Dermatitis</li> <li>○ .....Swelling of face and tongue and difficulty swallowing</li> <li>○ Flushing</li> <li>○ These events occurred as early as within 15 minutes of drug administration.</li> </ul> </li> </ul>
<p>Yaz (drospirenone and ethinyl estradiol) Tablets</p> <p>Prescribing Information</p> <p>Patient Package Insert</p>	<p><b>ADVERSE REACTIONS</b></p> <ul style="list-style-type: none"> <li>• The most frequent (&gt; 1%) treatment-emergent adverse events, listed in descending order, reported with the use of Yaz in the acne clinical trials.....</li> </ul> <p><b>PATIENT PACKAGE INSERT:</b> Brief Summary Patient Package Insert &amp; Detailed Patient Package Insert</p> <ul style="list-style-type: none"> <li>• Yaz may also be taken to treat moderate acne in women who are able to and wish to use the pill for birth control.</li> </ul>

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Minocin (minocycline hydrochloride) Pellet-Filled Capsules  Patient Package Insert	<b>PATIENT PACKAGE INSERT (new)</b>
Ovcon 35 Fe (norethindrone and ethinyl estradiol tablets, chewable and ferrous fumarate tablets)  Patient Package Insert	<b>PATIENT PACKAGE INSERT (new)</b>

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