



# FDA U.S. Food and Drug Administration

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## Safety

### October

#### Drug Safety Labeling Changes

The summary view includes drug products with safety labeling changes to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE sections. The "quick view" table below provides the drug name and sections modified. Click on the drug name to go to the detailed view. The detailed view includes sections and subsections modified, a description of new or modified safety information in the BOXED WARNING, CONTRAINDICATIONS, or WARNINGS sections, and a link to the revised prescribing information.

Key to Label Section Acronyms:

**BW=BOXED WARNING, C=CONTRAINDICATIONS, W=WARNINGS, P=PRECAUTIONS  
AR=ADVERSE REACTIONS, PPI/MG=PATIENT PACKAGE INSERT/MEDICATION GUIDE**

DRUG NAME (Click on drug name to go to detailed view)	SECTIONS MODIFIED					
	BW	C	W	P	AR	PPI/MG
Definity Vial for (Perflutren Lipid Microsphere) Injectable Suspension <sup>1</sup>	X		X	X	X	
Evamist (estradiol transdermal spray) <sup>2</sup>	X		X	X		PCI/PPI
Selzentry (maraviroc) Tablets <sup>3</sup> (Click on drug name to go to detailed view)	X		X	X		
	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>	<b>AR</b>	<b>PPI/MG</b>
Demerol (meperidine hydrochloride) <sup>4</sup>		X		X		
Oral Hycamtin (topotecan) Capsules <sup>5</sup>		X	X	X	X	
Premarin (conjugated estrogens tablets, USP) <sup>6</sup>		X	X			PPI
Suprenza (phentermine hydrochloride) ODT <sup>7</sup> (Click on drug name to go to detailed view)	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>	<b>AR</b>	<b>PPI/MG</b>
Amturnide (amlodipine/aliskiren/hydrochlorothiazide) Tablets <sup>8</sup>			X	X	X	
Avelox (moxifloxacin hydrochloride) Tablets and IV <sup>9</sup>			X	X		
Byetta (exenatide) injection <sup>10</sup>			X	X	X	PCI/MG
Clozaril (clozapine) Tablets <sup>11</sup>			X	X		
Ciprofloxacin Tablets			X			
Ciprofloxacin IV for Inusion Vial						
Ciprofloxacin 0.2 % Solution in 5% Dextrose						
Ciprofloxacin Oral Suspension						
Cipro XR Tablets <sup>12</sup>						
Factive (gemifloxacin mesylate) Tablets <sup>13</sup>			X			
Gallium Citrate Ga 67 Injection <sup>14</sup>			X			
Lactated Ringer's injection in aviva plastic container <sup>15</sup>			X	X	X	
Lactated Ringer's, <sup>16</sup>						
Lactated Ringer's and 5% Dextrose <sup>17</sup>						
Sodium Lactate (M/6 sodium lactate) injections in viaflex plastic container <sup>18</sup>						
Levaquin (levofloxacin) Tablets <sup>19</sup>			X	X		
Lithium Carbonate 150 mg, 300 mg, and 600 mg capsules <sup>20</sup>			X		X	PCI
Lithobid (lithium carbonate) Extended-Release tablets <sup>21</sup>			X		X	PCI
Nexavar (sorafenib) <sup>22</sup>			X	X	X	PCI
Noroxin (norfloxacin) Tablets <sup>23</sup>			X			
OxyContin (oxycodone hydrochloride) Controlled-Release Tablets <sup>24</sup>			X	X		
Tasigna (nilotinib) Capsules <sup>25</sup>			X	X		
Veramyst, (fluticasone furoate) Nasal Spray <sup>26</sup>			X	X	X	PCI
Votrient (pazopanib hydrochloride) Tablets <sup>27</sup>			X	X	X	MG
Vumon (teniposide) Injection <sup>28</sup>			X		X	
Vytorin (ezetimibe/simvastatin) Tablets <sup>29</sup>			X	X	X	PCI
Zocor (simvastatin) Tablets <sup>30</sup> (Click on drug name to go to detailed view)	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>	<b>AR</b>	<b>PPI/MG</b>
Accupril (quinapril hydrochloride) Tablets <sup>31</sup>				X		
Accuretic (quinapril HCl/hydrochlorothiazide) <sup>32</sup>				X		
Azor (amlodipine and olmesartan medoxomil) Tablets <sup>33</sup>				X		
Dexilant (dexlansoprazole) delayed-release capsules <sup>34</sup>				X		
Exforge (amlodipine/valsartan) Tablets <sup>35</sup>				X		
Exforge HCT (amlodipine/valsartan/hydrochlorothiazide) Tablets <sup>36</sup>				X		

Intence (etravirine) Tablets <sup>37</sup>					X			PPI
IXempra kit (ixabepilone) for injection <sup>38</sup>					X			
Leukeran (chlorambucil) Tablet <sup>39</sup>					X			
Lotrel (amlodipine besylate and benazepril hydrochloride) Capsules <sup>40</sup>					X			
Macugen (pegaptanib sodium injection) <sup>41</sup>					X			
Norvasc (amlodipine besylate) Tablets <sup>42</sup>					X			
Prevacid (lansoprazole) Delayed-Release Capsules and Prevacid Solutab (lansoprazole) Delayed-Release Orally Disintegrating Tablets <sup>43</sup>					X			
Protonix (pantoprazole sodium) For Delayed Release Oral Suspension and Delayed Release Tablets <sup>44</sup>					X			
Tekturna (aliskiren) Tablets <sup>45</sup> (Click on drug name to go to detailed view)	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>		<b>AR</b>	<b>PPI/MG</b>	
Prezista (darunavir) Tablets <sup>46</sup>						X		PPI
Reyataz (atazanavir sulfate) <sup>47</sup>						X		
Saphris (asenapine) sublingual Tablets <sup>48</sup>						X		
Sprycel (dasatinib) Tablets <sup>49</sup>						X		
Symbyax (olanzapine and fluoxetine HCl) <sup>50</sup> (Click on drug name to go to detailed view)	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>		<b>AR</b>	<b>PPI/MG</b>	
Humalog (insulin lispro injection) <sup>51</sup>								PPI
Humalog Mix 75/25 (75% insulin lispro protamine suspension/25% insulin lispro injection [rDNA origin])								
Humalog Mix 50/50 (50% insulin lispro protamine suspension/50 insulin lispro injection [rDNA origin]) <sup>52</sup>								

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