

[Home](#) [Safety](#) [MedWatch](#) [The FDA Safety Information and Adverse Event Reporting Program](#) [Safety Information](#)

Safety

July 2014

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					PPI/MG
	BW	C	W	P	AR	
Arixtra (fondaparinux sodium) Solution for Injection ¹	X		X	X		
Linzess (linaclotide) capsules ² (Click on drug name to go to detailed view)	X	X	X	X		PCI
Afinitor (everolimus) tablets for oral administration ³			X	X	X	
Afinitor Disperz (everolimus tablets for oral suspension) ⁴			X	X	X	
Anafranil (clomipramine) Capsules ⁵ <i>* risk of angle-closure glaucoma</i>			X	X	X	MG
Aptryxol (desvenlafaxine) extended-release Tablets ⁶ <i>* risk of angle-closure glaucoma</i>			X	X	X	MG
Aristocort Forte (Triamcinolone Diacetate, USP) Injectable Suspension ⁷ <i>* risk of serious neurologic adverse reactions with epidural administration</i>			X			
Aristospan (triamcinolone hexacetonide) Injection Suspension ⁸ <i>* risk of serious neurologic adverse reactions with epidural administration</i>			X			
Brintellix (vortioxetine) Tablets ⁹ <i>* risk of angle-closure glaucoma</i>			X	X	X	MG
Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) Injection Suspension ¹⁰ <i>* risk of serious neurologic adverse reactions with epidural administration</i>			X			
Celexa (citalopram hydrobromide) Tablets ¹¹ <i>* risk of angle-closure glaucoma</i>			X	X	X	MG

Cymbalta (duloxetine hydrochloride) Capsules¹²	X	X	X	MG
* risk of angle-closure glaucoma				
DEPO-MEDROL (methylprednisolone acetate injectable suspension, USP)¹³	X			
* risk of serious neurologic adverse reactions with epidural administration				
Desvenlafaxine Fumarate Extended-Release Tablets¹⁴	X	X	X	MG
* risk of angle-closure glaucoma				
Desyrel (trazodone hydrochloride) Tablets¹⁵	X	X	X	MG
* risk of angle-closure glaucoma				
Docetaxel Injection¹⁶	X	X	X	PCI
Effexor XR (venlafaxine hydrochloride) extended-release tablets¹⁷	X	X	X	MG
* risk of angle-closure glaucoma				
Fetzima (levomilnacipran) extended-release capsules¹⁸	X	X	X	MG
* risk of angle-closure glaucoma				
Fortical (calcitonin-salmon [rDNA origin]) Nasal Spray for Intranasal Use¹⁹	X	X	X	
Flomax (tamsulosin hydrochloride) Capsules²⁰	X	X	X	
Fluoxetine Tablets²¹	X	X	X	MG
* risk of angle-closure glaucoma				
Forfivo XL (bupropion hydrochloride Extended-Release Tablets²²	X	X	X	MG
* risk of angle-closure glaucoma				
Hexadrol (dexamethasone sodium phosphate) Injection²³	X			
* risk of serious neurologic adverse reactions with epidural administration				
Humatrope (somatropin [rDNA origin] for injection)²⁴	X	X		
Jakafi (ruxolitinib phosphate) Tablets²⁵	X	X		
Kadcyla (ado-trastuzumab emtansine) for injection, for intravenous Use²⁶	X	X	X	
Kenalog Injection (triamcinolone acetonide injectable suspension)²⁷	X			
* risk of serious neurologic adverse reactions with epidural administration				
Khedezla (desvenlafaxine base extended-release) Tablets²⁸	X	X	X	MG
* risk of angle-closure glaucoma				
Lexapro (escitalopram oxalate) Tablets and Oral Solution²⁹	X	X	X	MG
* risk of angle-closure glaucoma				
Luvox (fluvoxamine maleate) Tablets³⁰	X	X	X	MG
* risk of angle-closure glaucoma				

Luvox CR (fluvoxamine maleate) Extended-Release Capsules³¹	X	X	X	MG
* risk of angle-closure glaucoma				
Norpramin (desipramine hydrochloride tablets USP)³²	X	X	X	MG
* risk of angle-closure glaucoma				
Oleptro (trazodone hydrochloride) extended-release tablets³³	X	X	X	MG
* risk of angle-closure glaucoma				
Pamelor (nortriptyline HCl) Solution (Pamelor (nortriptyline HCl) Capsules³⁴)	X	X	X	MG
* risk of angle-closure glaucoma				
Paxil (paroxetine hydrochloride) tablets, oral suspension and controlled-release tablets³⁵	X	X	X	MG
* risk of angle-closure glaucoma				
Pexeva (paroxetine mesylate) Tablets³⁶	X	X	X	MG
* risk of angle-closure glaucoma				
Pristiq (desvenlafaxine) Extended-Release Tablets³⁷	X	X	X	MG
* risk of angle-closure glaucoma				
Prozac (fluoxetine hydrochloride) Delayed Release Capsules³⁸	X	X	X	MG
* risk of angle-closure glaucoma				
Prozac (fluoxetine hydrochloride) Pulvules³⁹	X	X	X	MG
* risk of angle-closure glaucoma				
Remeron (mirtazapine) Tablets Remeron SolTab orally disintegrating tablets⁴⁰	X	X	X	MG
* risk of angle-closure glaucoma				
Sinequan (doxepin hydrochloride) Capsules and Oral Concentrate⁴¹	X	X	X	MG
* risk of angle-closure glaucoma				
Solu-Cortef (hydrocortisone sodium succinate) Injection and Sterile Powder for Injection⁴²	X			
* risk of serious neurologic adverse reactions with epidural administration				
Solu-Medrol (methylprednisolone sodium succinate) Sterile Powder for Injection⁴³	X			
* risk of serious neurologic adverse reactions with epidural administration				
Surmontil (Trimipramine Maleate) Capsules⁴⁴	X	X	X	MG
* risk of angle-closure glaucoma				
Symbyax (olanzapine and fluoxetine hydrochloride) Capsules⁴⁵	X	X	X	MG
* risk of angle-closure glaucoma				
Tofranil-PM (imipramine pamoate) Capsules⁴⁶	X	X	X	MG
* risk of angle-closure glaucoma				

	BW	C	W	P	AR	PPI/MG
Trelstar (triptorelin pamoate for injectable suspension) Intramuscular use ⁴⁷			X	X		
Trileptal (oxcarbazepine) film-coated tablets and oral suspension for oral administration ⁴⁸			X	X		
Vantas (histrelin acetate) subcutaneous implant ⁴⁹	X		X			
Venlafaxine Hydrochloride Extended-Release Capsules ⁵⁰	X	X	X	X		MG
* risk of angle-closure glaucoma						
Victrelis (boceprevir) Capsules ⁵¹	X	X	X			MG
Viibryd (vilazodone hydrochloride) Tablets ⁵²	X	X	X	X		MG
* risk of angle-closure glaucoma						
Vivactil (protriptyline HCL) Tablets ⁵³	X	X	X	X		MG
* risk of angle-closure glaucoma						
Wellbutrin (bupropion hydrochloride) Wellbutrin SR and Wellbutrin XL Sustained-Release Tablets ⁵⁴	X	X	X	X		MG
* risk of angle-closure glaucoma						
Zelapar (selegiline hydrochloride) Orally Disintegrating Tablets ⁵⁵	X	X				
Zoloft (sertraline hydrochloride) Tablets and Oral Concentrate ⁵⁶	X	X	X	X		MG
* risk of angle-closure glaucoma						
(Click on drug name to go to detailed view)						
Azor (amlodipine and olmesartan medoxomil) tablets, for oral use ⁵⁷			X			
Edarbi (azilsartan medoxomil) Tablets ⁵⁸			X			
Edarbyclor (azilsartan medoxomil/chlorthalidone) Tablets ⁵⁹			X			
Effexor XR (venlafaxine hydrochloride) extended-release tablets ⁶⁰			X			
Excedrin Migraine (acetaminophen and caffeine) Tablets, Caplets and Geltabs ⁶¹			X			
Lupron (leuprolide acetate) Injection ⁶²			X			
Namenda XR (Memantine Hydrochloride Extended-Release) Capsules ⁶³			X			
Teveten (eprosartan mesylate) ⁶⁴			X			
Teveten HCT (eprosartan mesylate/hydrochlorothiazide) Tablets ⁶⁵			X			
(Click on drug name to go to detailed view)						
Adderall XR (dextroamphetamine mixed salts of a single entity amphetamine product) Capsules ⁶⁶				X		
Biaxin Filmtabs (clarithromycin tablets, USP)					X	
Biaxin Granules (clarithromycin for oral suspension USP)						
Biaxin XL Filmtabs (clarithromycin extended release tablets) ⁶⁷						
Cardene (nicardipine hydrochloride) Injection ⁶⁸				X		
Crestor (rosuvastatin calcium) tablets ⁶⁹				X		
Crixivan (indinavir sulfate) ⁷⁰				X		PI

Implanon (etonogestrel implant), For Subdermal Use ⁷¹	X
Nexplanon (etonogestrel implant), Radiopaque, Subdermal Use Only ⁷²	X
Vyvanse (lisdexamfetamine dimesylate) Capsules ⁷³	X

Page Last Updated: 08/15/2014

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewer and Players](#).

[Accessibility](#) [Contact FDA](#) [Careers](#) [FDA Basics](#) [FOIA](#) [No Fear Act Site Map](#) [Transparency Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Email FDA](#)



[For Government](#) [For Press](#)

[Combination Products Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#)
[Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry](#) [Health Professionals](#) [FDA Archive](#)



Links on this page:

1. [/Safety/MedWatch/SafetyInformation/ucm208639.htm](#)
2. [/Safety/MedWatch/SafetyInformation/ucm409253.htm](#)
3. [/Safety/MedWatch/SafetyInformation/ucm258494.htm](#)
4. [/Safety/MedWatch/SafetyInformation/ucm409257.htm](#)
5. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
6. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
7. [/Safety/MedWatch/SafetyInformation/ucm409825.htm](#)
8. [/Safety/MedWatch/SafetyInformation/ucm409825.htm](#)
9. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
10. [/Safety/MedWatch/SafetyInformation/ucm409825.htm](#)
11. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
12. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
13. [/Safety/MedWatch/SafetyInformation/ucm409825.htm](#)
14. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
15. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
16. [/Safety/MedWatch/SafetyInformation/ucm396551.htm](#)
17. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)
18. [/Safety/MedWatch/SafetyInformation/ucm409855.htm](#)

19. /Safety/MedWatch/SafetyInformation/ucm409251.htm
20. /Safety/MedWatch/SafetyInformation/ucm197087.htm
21. /Safety/MedWatch/SafetyInformation/ucm409855.htm
22. /Safety/MedWatch/SafetyInformation/ucm409855.htm
23. /Safety/MedWatch/SafetyInformation/ucm409825.htm
24. /Safety/MedWatch/SafetyInformation/ucm223890.htm
25. /Safety/MedWatch/SafetyInformation/ucm377314.htm
26. /Safety/MedWatch/SafetyInformation/ucm409252.htm
27. /Safety/MedWatch/SafetyInformation/ucm409825.htm
28. /Safety/MedWatch/SafetyInformation/ucm409855.htm
29. /Safety/MedWatch/SafetyInformation/ucm409855.htm
30. /Safety/MedWatch/SafetyInformation/ucm409855.htm
31. /Safety/MedWatch/SafetyInformation/ucm409855.htm
32. /Safety/MedWatch/SafetyInformation/ucm409855.htm
33. /Safety/MedWatch/SafetyInformation/ucm409855.htm
34. /Safety/MedWatch/SafetyInformation/ucm409855.htm
35. /Safety/MedWatch/SafetyInformation/ucm409855.htm
36. /Safety/MedWatch/SafetyInformation/ucm409855.htm
37. /Safety/MedWatch/SafetyInformation/ucm409855.htm
38. /Safety/MedWatch/SafetyInformation/ucm409855.htm
39. /Safety/MedWatch/SafetyInformation/ucm409855.htm
40. /Safety/MedWatch/SafetyInformation/ucm409855.htm
41. /Safety/MedWatch/SafetyInformation/ucm409855.htm
42. /Safety/MedWatch/SafetyInformation/ucm409825.htm
43. /Safety/MedWatch/SafetyInformation/ucm409825.htm
44. /Safety/MedWatch/SafetyInformation/ucm409855.htm
45. /Safety/MedWatch/SafetyInformation/ucm409855.htm
46. /Safety/MedWatch/SafetyInformation/ucm409855.htm
47. /Safety/MedWatch/SafetyInformation/ucm347049.htm
48. /Safety/MedWatch/SafetyInformation/ucm342622.htm
49. /Safety/MedWatch/SafetyInformation/ucm242305.htm
50. /Safety/MedWatch/SafetyInformation/ucm409855.htm
51. /Safety/MedWatch/SafetyInformation/ucm303600.htm
52. /Safety/MedWatch/SafetyInformation/ucm409855.htm
53. /Safety/MedWatch/SafetyInformation/ucm409855.htm
54. /Safety/MedWatch/SafetyInformation/ucm409855.htm

55. /Safety/MedWatch/SafetyInformation/ucm409200.htm
56. /Safety/MedWatch/SafetyInformation/ucm409855.htm
57. /Safety/MedWatch/SafetyInformation/ucm258787.htm
58. /Safety/MedWatch/SafetyInformation/ucm286297.htm
59. /Safety/MedWatch/SafetyInformation/ucm396553.htm
60. /Safety/MedWatch/SafetyInformation/ucm319226.htm
61. /Safety/MedWatch/SafetyInformation/ucm409256.htm
62. /Safety/MedWatch/SafetyInformation/ucm409254.htm
63. /Safety/MedWatch/SafetyInformation/ucm409255.htm
64. /Safety/MedWatch/SafetyInformation/ucm258489.htm
65. /Safety/MedWatch/SafetyInformation/ucm258785.htm
66. /Safety/MedWatch/SafetyInformation/ucm233812.htm
67. /Safety/MedWatch/SafetyInformation/ucm181715.htm
68. /Safety/MedWatch/SafetyInformation/ucm200269.htm
69. /Safety/MedWatch/SafetyInformation/ucm200635.htm
70. /Safety/MedWatch/SafetyInformation/ucm409206.htm
71. /Safety/MedWatch/SafetyInformation/ucm400440.htm
72. /Safety/MedWatch/SafetyInformation/ucm400441.htm
73. /Safety/MedWatch/SafetyInformation/ucm234015.htm