

CDER Prescription Drug Labeling Conference
December 4th and 5th 2019



Labeling Finalization: Recommendations for Final Check of Prescribing Information Format and Appearance

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Office of New Drugs | CDER | US FDA

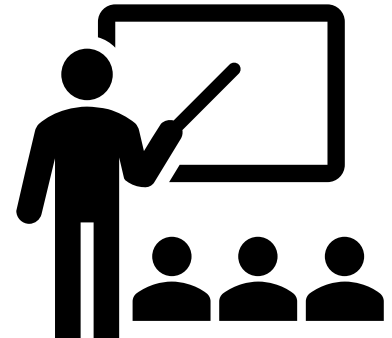
Disclaimer



- The views expressed in this presentation are those of the speaker, and do not necessarily represent an official FDA position
- The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates

Learning Objectives

- Understand labeling quality and important format/appearance issues that can arise
 - Learn to identify and correct the 5 common format¹ issues in the Prescribing Information

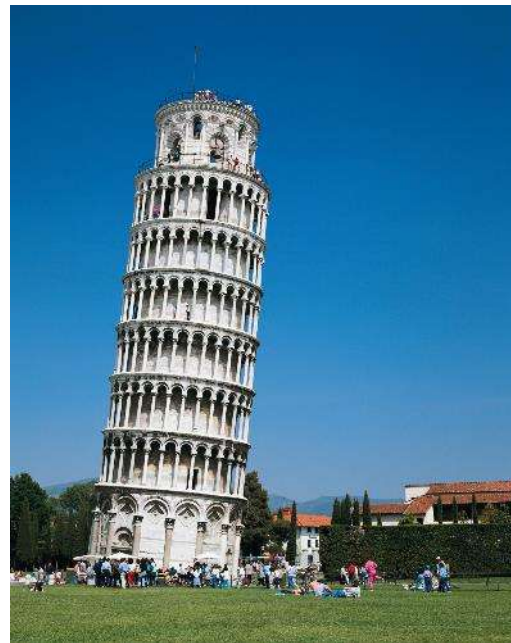


1. This presentation will not focus on content issues
www.fda.gov

Importance of Quality



VS

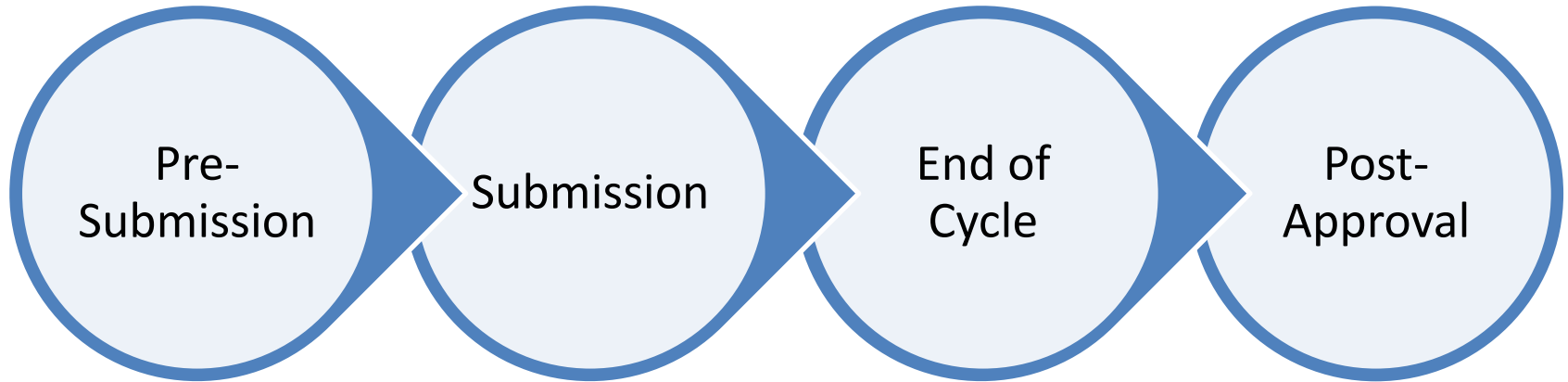


CDER Cares About Quality Too!



- Prescription Drug Labeling is CDER's primary tool for communicating drug information
- CDER has developed an internal process to identify and correct Prescribing Information format/appearance issues
 - Labeling review specialists
 - Multiple types of internal labeling training
 - Collaborative review of the Prescribing Information
 - Access to various labeling format/appearances resources (e.g. Selected Requirements of Prescribing Information)

CDER Looks for Every Opportunity to Increase Format Quality



Post Approval Labeling Quality Review Is Key

- Quality is based on labeling regulations and guidances, scientific content, and format/appearance
- We evaluate overall labeling format/appearance quality routinely
 - Publicly available approved labeling (Drugs@FDA)
 - Reviewed approximately 1400 PLR labeling in the past year¹

1. Last approved labeling for all CDER regulated NDA and BLA products with PLR labeling. CBER products are not included on Drugs@FDA. Did not include ANDA products

Labeling Format/Appearance Analysis Summary of All Approved PLR Labeling



- Of the 1400 PLR labeling the majority do not have format/appearance issues
- Of the labeling that do contain significant format/appearance issues; a noticeable trend arose. These 5 issues will be the focus of my presentation today
 - Significant format/appearance issues are confusing and distract from information in the Prescribing Information

Suboptimal Labeling

- May decrease confidence in quality of all FDA-approved labeling.
- May distract from required and recommended information in labeling.
- May diverge from regulatory requirements and guidance recommendations.



Challenge Question: Can You Find the 5
Major Format Issues in the Following
Labeling?



Highlights of Prescribing Information (Highlights)

1 HIGHLIGHTS OF PRESCRIBING INFORMATION
2 These highlights do not include all the information needed to use
3 PROPRIETARY NAME safely and effectively. See full prescribing
4 information for PROPRIETARY NAME.
5
6 PROPRIETARY NAME (nonproprietary name) dosage form, route
7 of administration, controlled substance symbol
8 Initial U.S. Approval: XXXX
9
10 **WARNING: TITLE OF WARNING**
11 See full prescribing information for complete boxed warning.
12 • Text (4)
13 • Text (5.x)
14
15 RECENT MAJOR CHANGES
16 Section Title, Subsection Title (x.x) M/YYYY
17 Section Title, Subsection Title (x.x) M/YYYY
18
19 INDICATIONS AND USAGE
20 PROPRIETARY NAME is a (insert FDA established pharmacologic
21 class text phrase) indicated for ... (1)
22 Limitations of Use
23 Text (1)
24
25 DOSAGE AND ADMINISTRATION
26 • Text (2.x)
27 • Text (2.x)
28
29 DOSAGE FORMS AND STRENGTHS
30 Dosage form(s), strength(s) (2)
31
32 CONTRAINDICATIONS
33 • Text (4)
34 • Text (4)
35
36 WARNINGS AND PRECAUTIONS
37 • Text (5.x)
38 • Text (5.x)
39
40 ADVERSE REACTIONS
41 Most common adverse reactions (incidence > x%) are text (5.x)
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43 To report SUSPECTED ADVERSE REACTIONS, contact name of
44 manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or
45 www.fda.gov/medwatch.
46
47 DRUG INTERACTIONS
48 • Text (7.x)
49 • Text (7.x)
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51 USE IN SPECIFIC POPULATIONS
52 • Text (8.x)
53 • Text (8.x)
54
55 See 17 for PATIENT COUNSELING INFORMATION and
56 FDA-approved patient labeling OR and Medication Guide.
57 Revised: 4/2017

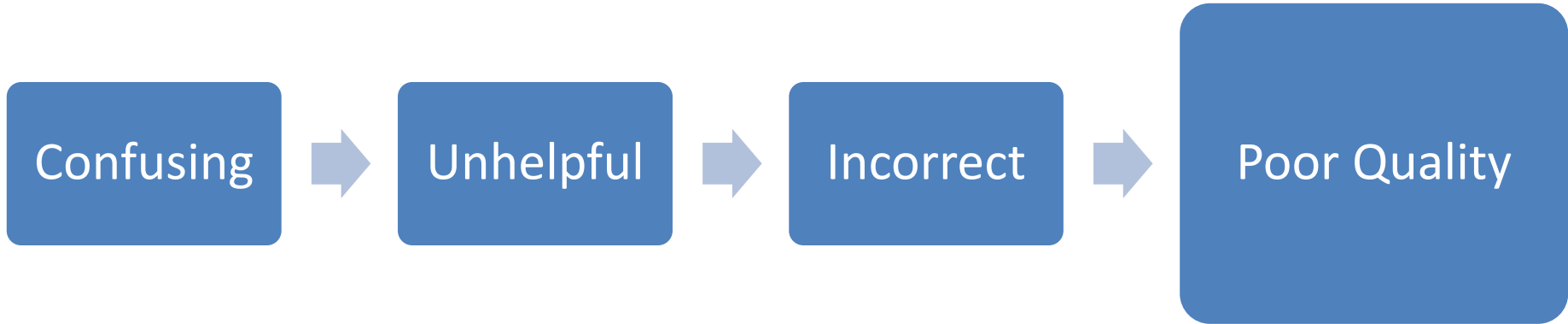
Full Prescribing Information: Contents (Table of Contents)

58 FULL PRESCRIBING INFORMATION: CONTENTS*
59 WARNING: TITLE OF WARNING
60 1 INDICATIONS AND USAGE
61 2 DOSAGE AND ADMINISTRATION
62 2.1 Subsection Title
63 2.2 Subsection Title
64 3 DOSAGE FORMS AND STRENGTHS
65 4 CONTRAINDICATIONS
66 5 WARNINGS AND PRECAUTIONS
67 5.1 Subsection Title
68 5.2 Subsection Title
69 6 ADVERSE REACTIONS
70 6.1 Clinical Trials Experience
71 6.2 Immunogenicity
72 6.2 or 6.3 Postmarketing Experience
73 7 DRUG INTERACTIONS
74 7.1 Subsection Title
75 7.2 Subsection Title
76 8 USE IN SPECIFIC POPULATIONS
77 8.1 Pregnancy
78 8.2 Lactation (if not required to be in PLLR format use Labor and Delivery)
79 8.3 Females and Males of Reproductive Potential (if not required to be in PLLR format use Nursing Mothers)
80 8.4 Pediatric Use
81 8.5 Geriatric Use
82 8.6 Subpopulation X
83
84
85

1. Annotations

<div style="border: 1px solid black; padding: 2px; width: fit-content;"> NDA 12345-5 123 NDA 6789-5 789 Page 3 of 55 </div>	<div style="border: 1px solid black; padding: 2px; width: fit-content;"> Confidential Draft 1.58.2A 3/11/2017 </div>
<p>100 FULL PRESCRIBING INFORMATION (FPI) CONTAINS THE FOLLOWING INFORMATION:</p> <p>101 These suggestions do not include all the information needed to use</p> <p>102 PROPRIO BRAND NAME (or proprietary name) and strength. See full prescribing</p> <p>103 information for PROPRIO BRAND NAME.</p> <p>104 PROPRIO BRAND NAME (or proprietary name) dosage form, strength,</p> <p>105 and U.S. Approved XXXX</p>	<p>106 _____ INDICATIONS AND USAGE _____</p> <p>107 Dosage form, strength(s):</p> <p>108 _____</p> <p>109 _____</p> <p>110 _____</p> <p>111 _____</p> <p>112 _____</p> <p>113 _____</p> <p>114 _____</p> <p>115 _____</p> <p>116 _____</p> <p>117 _____</p> <p>118 _____</p> <p>119 _____</p> <p>120 _____</p> <p>121 _____</p> <p>122 _____</p> <p>123 _____</p> <p>124 _____</p> <p>125 _____</p> <p>126 _____</p> <p>127 _____</p> <p>128 _____</p> <p>129 _____</p> <p>130 _____</p> <p>131 _____</p> <p>132 _____</p> <p>133 _____</p> <p>134 _____</p> <p>135 _____</p> <p>136 _____</p> <p>137 _____</p> <p>138 _____</p> <p>139 _____</p> <p>140 _____</p> <p>141 _____</p> <p>142 _____</p> <p>143 _____</p> <p>144 _____</p> <p>145 _____</p> <p>146 _____</p> <p>147 _____</p> <p>148 _____</p> <p>149 _____</p> <p>150 _____</p> <p>151 _____</p> <p>152 _____</p> <p>153 _____</p> <p>154 _____</p> <p>155 _____</p> <p>156 _____</p> <p>157 _____</p> <p>158 _____</p> <p>159 _____</p> <p>160 _____</p> <p>161 _____</p> <p>162 _____</p> <p>163 _____</p> <p>164 _____</p> <p>165 _____</p> <p>166 _____</p> <p>167 _____</p> <p>168 _____</p> <p>169 _____</p> <p>170 _____</p> <p>171 _____</p> <p>172 _____</p> <p>173 _____</p> <p>174 _____</p> <p>175 _____</p> <p>176 _____</p> <p>177 _____</p> <p>178 _____</p> <p>179 _____</p> <p>180 _____</p> <p>181 _____</p> <p>182 _____</p> <p>183 _____</p> <p>184 _____</p> <p>185 _____</p> <p>186 _____</p> <p>187 _____</p> <p>188 _____</p> <p>189 _____</p> <p>190 _____</p> <p>191 _____</p> <p>192 _____</p> <p>193 _____</p> <p>194 _____</p> <p>195 _____</p> <p>196 _____</p> <p>197 _____</p> <p>198 _____</p> <p>199 _____</p> <p>200 _____</p>
<p>201 FULL PRESCRIBING INFORMATION (FPI) CONTAINS THE FOLLOWING INFORMATION:</p> <p>202 1 INDICATIONS AND USAGE</p> <p>203 2 DOSAGE AND ADMINISTRATION</p> <p>204 2.1 Subsection Title</p> <p>205 2.2 Subsection Title</p> <p>206 3 CONTRAINDICATIONS</p> <p>207 4 WARNINGS AND PRECAUTIONS</p> <p>208 4.1 Subsection Title</p> <p>209 4.2 Subsection Title</p> <p>210 5 ADVERSE REACTIONS</p> <p>211 5.1 Clinical Study Experience</p> <p>212 5.2 Immunogenicity</p> <p>213 5.3 or 5.4 Postmarketing Experience</p> <p>214 6 DRUG INTERACTIONS</p> <p>215 6.1 Subsection Title</p> <p>216 6.2 Subsection Title</p> <p>217 6.3 or 6.4 Subsection Title</p> <p>218 7 USE IN SPECIFIC POPULATIONS</p> <p>219 7.1 Pregnancy</p> <p>220 7.2 Lactation (if not required, state in FULL PRESCRIBING INFORMATION)</p> <p>221 7.3 Pediatric Use</p> <p>222 7.4 Geriatric Use</p> <p>223 7.5 Subsection Title</p>	<p>224 _____</p> <p>225 _____</p> <p>226 _____</p> <p>227 _____</p> <p>228 _____</p> <p>229 _____</p> <p>230 _____</p> <p>231 _____</p> <p>232 _____</p> <p>233 _____</p> <p>234 _____</p> <p>235 _____</p> <p>236 _____</p> <p>237 _____</p> <p>238 _____</p> <p>239 _____</p> <p>240 _____</p> <p>241 _____</p> <p>242 _____</p> <p>243 _____</p> <p>244 _____</p> <p>245 _____</p> <p>246 _____</p> <p>247 _____</p> <p>248 _____</p> <p>249 _____</p> <p>250 _____</p> <p>251 _____</p> <p>252 _____</p> <p>253 _____</p> <p>254 _____</p> <p>255 _____</p> <p>256 _____</p> <p>257 _____</p> <p>258 _____</p> <p>259 _____</p> <p>260 _____</p> <p>261 _____</p> <p>262 _____</p> <p>263 _____</p> <p>264 _____</p> <p>265 _____</p> <p>266 _____</p> <p>267 _____</p> <p>268 _____</p> <p>269 _____</p> <p>270 _____</p> <p>271 _____</p> <p>272 _____</p> <p>273 _____</p> <p>274 _____</p> <p>275 _____</p> <p>276 _____</p> <p>277 _____</p> <p>278 _____</p> <p>279 _____</p> <p>280 _____</p> <p>281 _____</p> <p>282 _____</p> <p>283 _____</p> <p>284 _____</p> <p>285 _____</p> <p>286 _____</p> <p>287 _____</p> <p>288 _____</p> <p>289 _____</p> <p>290 _____</p> <p>291 _____</p> <p>292 _____</p> <p>293 _____</p> <p>294 _____</p> <p>295 _____</p> <p>296 _____</p> <p>297 _____</p> <p>298 _____</p> <p>299 _____</p> <p>300 _____</p>

1. Annotations





1 HIGHLIGHTS OF PRESCRIBING INFORMATION
2 These highlights do not include all the information needed to use
3 PROPRIETARY NAME safely and effectively. See full prescribing
4 information for PROPRIETARY NAME.

5 PROPRIETARY NAME (nonproprietary name) dosage form, route
6 of administration, controlled substance symbol
7 Initial U.S. Approval: XXXX
8
9

10 **WARNING: TITLE OF WARNING**
11 See full prescribing information for complete boxed warning.
12 • Text (4)
13 • Text (5.x)

14 **RECENT MAJOR CHANGES**
15 Section Title, Subsection Title (x.x) M/YYYY
16 Section Title, Subsection Title (x.x) M/YYYY

17 **INDICATIONS AND USAGE**
18 PROPRIETARY NAME is a (insert FDA established pharmacologic
19 class text phrase) indicated for ... (1)

20 **Limitations of Use**
21 Text (1)

22 **DOSAGE AND ADMINISTRATION**
23 • Text (2.x)
24 • Text (2.x)
25

26 **DOSAGE FORMS AND STRENGTHS**
27 Dosage form(s), strength(s) (2)

28 **CONTRAINDICATIONS**
29
30 • Text (4)
31 • Text (4)

32 **WARNINGS AND PRECAUTIONS**
33
34 • Text (5.x)
35 • Text (5.x)

36 **ADVERSE REACTIONS**
37 Most common adverse reactions (incidence > x%) are text (5.x)

38 To report SUSPECTED ADVERSE REACTIONS, contact name of
39 manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or
40 www.fda.gov/medwatch.

41 **DRUG INTERACTIONS**
42
43 • Text (7.x)
44 • Text (7.x)

45 **USE IN SPECIFIC POPULATIONS**
46
47 • Text (8.x)
48 • Text (8.x)

49 See 17 for PATIENT COUNSELING INFORMATION and
50 FDA-approved patient labeling OR and Medication Guide.

51 Revised: 4/2017

58 FULL PRESCRIBING INFORMATION: CONTENTS*

59 **WARNING: TITLE OF WARNING**

60 **1 INDICATIONS AND USAGE**

61 **2 DOSAGE AND ADMINISTRATION**

62 2.1 Subsection Title

63 2.2 Subsection Title

64 **3 DOSAGE FORMS AND STRENGTHS**

65 **4 CONTRAINDICATIONS**

66 **5 WARNINGS AND PRECAUTIONS**

67 5.1 Subsection Title

68 5.2 Subsection Title

69 **6 ADVERSE REACTIONS**

70 6.1 Clinical Trials Experience

71 6.2 Immunogenicity

72 6.2 or 6.3 Postmarketing Experience

73 **7 DRUG INTERACTIONS**

74 7.1 Subsection Title

75 7.2 Subsection Title

76 **8 USE IN SPECIFIC POPULATIONS**

77 8.1 Pregnancy

78 8.2 Lactation (if not required to be in PLLR format use Labor and Delivery)

79 8.3 Females and Males of Reproductive Potential (if not required to be in PLLR format use Nursing Mothers)

80 8.4 Pediatric Use

81 8.5 Geriatric Use

82 8.6 Subpopulation X

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2. Line Numbers

	<p>ANDA 21405-023 ANDA 6780-9 789 Page 1 of 33</p> <p>HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use and understand TRIVY HMRB safely and effectively. See the prescribing information for PRODOTINIV HMRB.</p> <p>PRODOTINIV HMRB (propionylglycyl-L-proline form, ester, of amoxicillin, immediate-release oral suspension) (oral U.S. Suspension) XR33</p> <p>WARNING: TITLE OF WARNING See full prescribing information for complete disease warning.</p> <ul style="list-style-type: none"> • Text (14) • Text (16) <p>ADVERSE REACTIONS See full prescribing information for complete adverse reactions. To report SUSPECTED ADVERSE REACTIONS, contact Merck or manufacturer at 1-800-526-7899 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.</p> <p>DRUG INTERACTIONS</p> <ul style="list-style-type: none"> • Text (17) • Text (17) <p>USE IN SPECIFIC POPULATIONS</p> <ul style="list-style-type: none"> • Text (18) • Text (18) <p>See full PATIENT COUNSELING INFORMATION and FDA-approved patient labeling (PI and Medication Guide).</p> <p>Revised: 4/2011</p>	<p>20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57</p>
<p>58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85</p>	<p>FULL PRESCRIBING INFORMATION CONTENTS</p> <p>WARNING: TITLE OF WARNING</p> <p>1 INDICATIONS AND USAGE</p> <p>2 DOSAGE AND ADMINISTRATION</p> <ul style="list-style-type: none"> 2.1 Suspension Title 2.2 Suspension Title <p>3 DOSAGE FORMS AND STRENGTHS</p> <p>4 CONTRAINDICATIONS</p> <p>5 WARNINGS AND PRECAUTIONS</p> <ul style="list-style-type: none"> 5.1 Suspension Title 5.2 Suspension Title <p>6 ADVERSE REACTIONS</p> <ul style="list-style-type: none"> 6.1 Clinical Trial Experience 6.2 Postmarketing 6.3 Postmarketing Commitment <p>7 DRUG INTERACTIONS</p> <ul style="list-style-type: none"> 7.1 Suspension Title 7.2 Suspension Title <p>8 USE IN SPECIFIC POPULATIONS</p> <ul style="list-style-type: none"> 8.1 Pregnancy 8.2 Lactation (if not required to be in PLN format use Lactation Labeling) 8.3 Pediatric and Elderly (if appropriate for use; if not required to be in PLN format use Elderly Patients) 8.4 Pediatric Use 8.5 Geriatric Use 8.6 Subpopulations 	



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2 These highlights do not include all the information needed to use
3 PROPRIETARY NAME safely and effectively. See full prescribing
4 information for PROPRIETARY NAME.

5 PROPRIETARY NAME (nonproprietary name) dosage form, route
6 of administration, controlled substance symbol
7 Initial U.S. Approval: XXXX
8

9
10 **WARNING: TITLE OF WARNING**
11 See full prescribing information for complete boxed warning.
12 • Text (4)
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14
15 **RECENT MAJOR CHANGES**
16 Section Title, Subsection Title (x.x) M/YYYY
17 Section Title, Subsection Title (x.x) M/YYYY

18
19 **INDICATIONS AND USAGE**
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21 class text phrase) indicated for ... (1)

22 Limitations of Use
23 Text (1)

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26 • Text (2.x)
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37 Most common adverse reactions (incidence > x%) are text (5.x)

38 To report SUSPECTED ADVERSE REACTIONS, contact name of
39 manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or
40 www.fda.gov/medwatch.

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42 **DRUG INTERACTIONS**
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47 • Text (8.x)
48 • Text (8.x)

49 See 17 for PATIENT COUNSELING INFORMATION and
50 FDA-approved patient labeling OR and Medication Guide.
51
52
53
54
55 Revised: 4/2017
56
57

58 FULL PRESCRIBING INFORMATION: CONTENTS*

59 WARNING: TITLE OF WARNING

60 1 INDICATIONS AND USAGE

61 2 DOSAGE AND ADMINISTRATION

62 2.1 Subsection Title

63 2.2 Subsection Title

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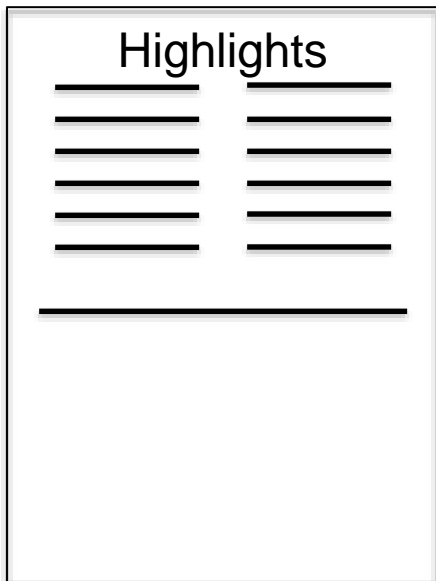
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3. Number of Columns

	NDA 12345-123	Conditional
	NDA 6789-5 789	Drugs 1.58.2A
	Page 3 of 53	3-11-2017
1	HIGHLIGHTS OF PRESCRIBING INFORMATION	
2	These highlights do not include all the information needed to use	
3	PROPRIETARY NAME safely and effectively. See full prescribing	
4	information for PROPRIETARY NAME.	
5		
6	PROPRIETARY NAME (Proprietary name; dosage form; trade	
7	name of administration; controlled substance symbol)	
8	Initial U.S. Approval: XXXX	
9		
10	WARNING: TITLE OF WARNING	
11	See full prescribing information for complete boxed warning.	
12	• Text (4)	
13	• Text (5.a)	
14		
15	RECENT MAJOR CHANGES	
16	Section Title, Subsection Title (s)	MM/YY
17	Section Title, Subsection Title (s)	MM/YY
18		
19	INDICATIONS AND USAGE	
20	PROPRIETARY NAME is a (brand/ FDA established combination)	
21	(state full generic equivalent(s) ... (3))	
22	Limitations of use:	
23	Text (1)	
24		
25	DOSE AND ADMINISTRATION	
26	• Text (2.a)	
27	• Text (2.c)	
28		
29	DOSE FORMS AND STRENGTHS	
30	Dosage form(s), strength(s)	
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3. Number of Columns



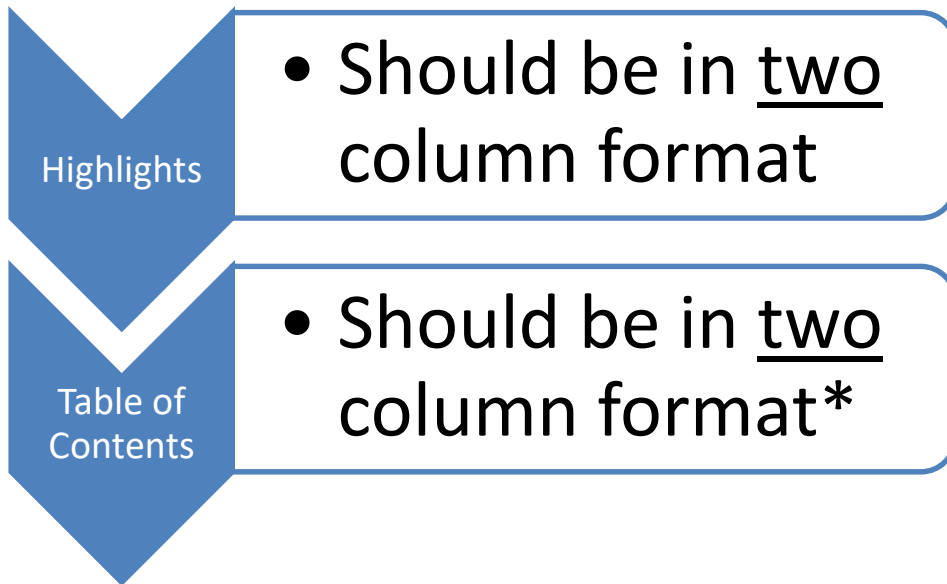
Highlights

- Should be in two column format*

* 21 CFR 201.57(d)(8) and guidance for industry: Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements (February 2013)

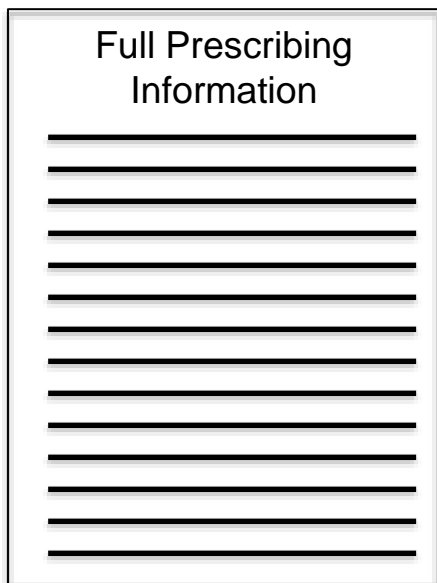
3. Number of Columns

Table of Contents	
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* Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements (February 2013)

3. Number of Columns



Highlights

- Should be in two column format

Table of Contents

- Should be in two column format

Full Prescribing Information

- Consider putting into one column format



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25

RECENT MAJOR CHANGES

Section Title, Subsection Title (x.x) M/YYYY
Section Title, Subsection Title (x.x) M/YYYY

INDICATIONS AND USAGE

PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for ... (1)

Limitations of Use
Text (1)

DOSAGE AND ADMINISTRATION

- Text (2.x)
- Text (2.x)

DOSAGE FORMS AND STRENGTHS

Dosage form(s), strength(s) (2)

CONTRAINDICATIONS

- Text (4)
- Text (4)

WARNINGS AND PRECAUTIONS

- Text (5.x)
- Text (5.x)

ADVERSE REACTIONS

Most common adverse reactions (incidence > x%) are text (5.x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Text (7.x)
- Text (7.x)

USE IN SPECIFIC POPULATIONS

- Text (8.x)
- Text (8.x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: 4/2017

58 FULL PRESCRIBING INFORMATION: CONTENTS*

59 WARNING: TITLE OF WARNING

60 1 INDICATIONS AND USAGE

61 2 DOSAGE AND ADMINISTRATION

62 2.1 Subsection Title

63 2.2 Subsection Title

64 3 DOSAGE FORMS AND STRENGTHS

65 4 CONTRAINDICATIONS

66 5 WARNINGS AND PRECAUTIONS

67 5.1 Subsection Title

68 5.2 Subsection Title

69 6 ADVERSE REACTIONS

70 6.1 Clinical Trials Experience

71 6.2 Immunogenicity

72 6.2 or 6.3 Postmarketing Experience

73 7 DRUG INTERACTIONS

74 7.1 Subsection Title

75 7.2 Subsection Title

76 8 USE IN SPECIFIC POPULATIONS

77 8.1 Pregnancy

78 8.2 Lactation (if not required to be in PLLR format use Labor and Delivery)

79 8.3 Females and Males of Reproductive Potential (if not required to be in PLLR format use Nursing Mothers)

80 8.4 Pediatric Use

81 8.5 Geriatric Use

82 8.8 Subpopulation X

83

84

85

4. Correct Dates

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83</p>	<p>NDA 123456 123 NDA e789 S 789 Page 3 of 35</p> <p>HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.</p> <p>PROPRIETARY NAME (proprietary name) dosage form, route of administration</p> <p>Initial U.S. Approval: XXXX</p> <p>WARNING: TITLE OF WARNING See full prescribing information for complete boxed warning.</p> <ul style="list-style-type: none"> • Text (4) • Text (5.x) <p>RECENT MAJOR CHANGES Section Title, Subsection Title (x.x) M/YYYY Section Title, Subsection Title (x.x) M/YYYY</p> <p>INDICATIONS AND USAGE PROPRIETARY NAME is a (insert FDA-identified pharmacologic class) (insert phrase) indicated for (1).</p> <p>Limitations of use Text (1).</p> <p>DOSEAGE AND ADMINISTRATION</p> <ul style="list-style-type: none"> • Text (2.x) • Text (2.x) 	<p>Confidential Drug 1-AB-7-A 3/11/2017</p> <p>DOSEAGE FORMS AND STRENGTHS Dosage form(s), strength(s) (1)</p> <p>CONTRAINDICATIONS</p> <ul style="list-style-type: none"> • Text (6) • Text (6) <p>WARNINGS AND PRECAUTIONS</p> <ul style="list-style-type: none"> • Text (5.y) • Text (5.x) <p>ADVERSE REACTIONS Most common adverse reactions (incidence = x%) are text (5.x).</p> <p>To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer, at toll-free phone 8 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.</p> <p>DRUG INTERACTIONS</p> <ul style="list-style-type: none"> • Text (7.x) • Text (7.x) <p>USE IN SPECIFIC POPULATIONS</p> <ul style="list-style-type: none"> • Text (8.y) • Text (8.x) <p>See (7) for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling (OR and Medication Guide).</p> <p>Revised: 4/2017</p>
<p>58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83</p>	<p>FULL PRESCRIBING INFORMATION CONTENTS*</p> <p>1. WARNING: TITLE OF WARNING</p> <p>2. INDICATIONS AND USAGE</p> <p>3. DOSEAGE AND ADMINISTRATION</p> <p>3.1 Subsection Title</p> <p>3.2 Subsection Title</p> <p>4. CONTRAINDICATIONS</p> <p>5. WARNINGS AND PRECAUTIONS</p> <p>5.1 Subsection Title</p> <p>5.2 Subsection Title</p> <p>6. ADVERSE REACTIONS</p> <p>6.1 Clinical Trial Experience</p> <p>6.2 or 6.3 Postmarketing Experience</p> <p>7. DRUG INTERACTIONS</p> <p>7.1 Subsection Title</p> <p>7.2 Subsection Title</p> <p>8. USE IN SPECIFIC POPULATIONS</p> <p>8.1 Pregnancy</p> <p>8.2 Lactation (if you require to see in PLP, format use Lactation Delivery)</p> <p>8.3 Fertility and Male or Reproductive Potential (if not required to be in PLP, format use Having Mother)</p> <p>8.4 Pediatric Use</p> <p>8.5 Geriatric Use</p> <p>8.6 Subpopulations</p>	

4. Correct Dates

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NDA 6789/S 789
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Draft 1.58.2A
3/11/2017

<p>1 HIGHLIGHTS OF PRESCRIBING INFORMATION</p> <p>2 These highlights do not include all the information needed to use</p> <p>3 PROPRIETARY NAME safely and effectively. See full prescribing</p> <p>4 information for PROPRIETARY NAME.</p> <p>5</p> <p>6 PROPRIETARY NAME (nonproprietary name) dosage form, route</p> <p>7 of administration, controlled substance symbol</p> <p>8 Initial U.S. Approval: XXXX</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>9 WARNING: TITLE OF WARNING</p> <p>10 See full prescribing information for complete boxed warning.</p> <ul style="list-style-type: none"> 11 • Text (4) 12 • Text (5.x) </div> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>26 -----DOSAGE FORMS AND STRENGTHS-----</p> <p>27 Dosage form(s): strength(s) (3)</p> <p>28</p> <p>29 -----CONTRAINDICATIONS-----</p> <p>30 • Text (4)</p> <p>31 • Text (4)</p> <p>32</p> <p>33 -----WARNINGS AND PRECAUTIONS-----</p> <p>34 • Text (5.x)</p> <p>35 • Text (5.x)</p> <p>36</p> <p>37 -----ADVERSE REACTIONS-----</p> <p>38 Most common adverse reactions (incidence > x%) are text (6.x)</p> <p>39</p> <p>40 To report SUSPECTED ADVERSE REACTIONS, contact name of</p> <p>41 manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or</p> <p>42 www.fda.gov/medwatch.</p> <p>43</p> <p>44 -----DRUG INTERACTIONS-----</p> <p>45 • Text (7.x)</p> <p>46 • Text (7.x)</p> <p>47</p> <p>48 -----USE IN SPECIFIC POPULATIONS-----</p> <p>49 • Text (8.x)</p> <p>50 • Text (8.x)</p> <p>51</p> <p>52 See 17 for PATIENT COUNSELING INFORMATION and</p> <p>53 FDA-approved patient labeling OR and Medication Guide.</p> <p>54</p> <p>55</p> <p>56</p> <p>57</p> <p style="text-align: right;">Revised: 4/2017</p>
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Never updated

Conflicting



1 HIGHLIGHTS OF PRESCRIBING INFORMATION
2 These highlights do not include all the information needed to use
3 PROPRIETARY NAME safely and effectively. See full prescribing
4 information for PROPRIETARY NAME.

5 PROPRIETARY NAME (nonproprietary name) dosage form, route
6 of administration, controlled substance symbol
7 Initial U.S. Approval: XXXX
8
9

10
11 **WARNING: TITLE OF WARNING**
12 See full prescribing information for complete boxed warning.
13
14 • Text (4)
15 • Text (5.x)

16
17 **RECENT MAJOR CHANGES**
18 Section Title, Subsection Title (x,x) M/YYYY
19 Section Title, Subsection Title (x,x) M/YYYY
20

21 **INDICATIONS AND USAGE**
22 PROPRIETARY NAME is a (insert FDA established pharmacologic
23 class text phrase) indicated for ... (1)
24

25 **Limitations of Use**
26 Text (1)

27 **DOSAGE AND ADMINISTRATION**
28 • Text (2.x)
29 • Text (2.x)

30 **DOSAGE FORMS AND STRENGTHS**
31 Dosage form(s), strength(s) (2)

32 **CONTRAINDICATIONS**
33 • Text (4)
34 • Text (4)

35 **WARNINGS AND PRECAUTIONS**
36 • Text (5.x)
37 • Text (5.x)

38 **ADVERSE REACTIONS**
39 Most common adverse reactions (incidence > x%) are text (5.x)

40 To report SUSPECTED ADVERSE REACTIONS, contact name of
41 manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or
42 www.fda.gov/medwatch.

43 **DRUG INTERACTIONS**
44 • Text (7.x)
45 • Text (7.x)

46 **USE IN SPECIFIC POPULATIONS**
47 • Text (8.x)
48 • Text (8.x)

49 See 17 for PATIENT COUNSELING INFORMATION and
50 FDA-approved patient labeling OR and Medication Guide.

51 Revised: 4/2017

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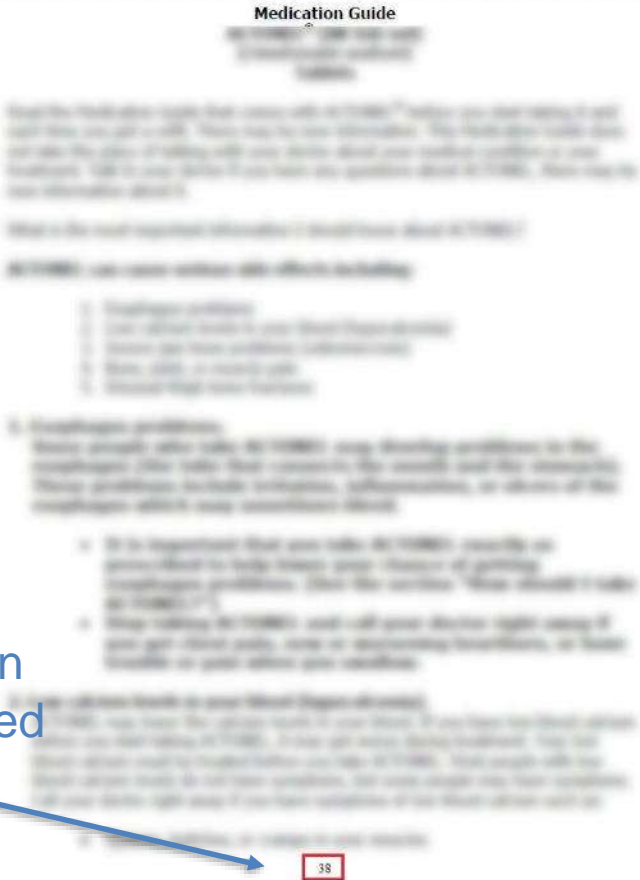
58 **FULL PRESCRIBING INFORMATION CONTENTS***
59 **WARNING: TITLE OF WARNING**
60 **1 INDICATIONS AND USAGE**
61 **2 DOSAGE AND ADMINISTRATION**
62 2.1 Subsection Title
63 2.2 Subsection Title
64 **3 DOSAGE FORMS AND STRENGTHS**
65 **4 CONTRAINDICATIONS**
66 **5 WARNINGS AND PRECAUTIONS**
67 5.1 Subsection Title
68 5.2 Subsection Title
69 **6 ADVERSE REACTIONS**
70 6.1 Clinical Trials Experience
71 6.2 Immunogenicity
72 6.2 or 6.3 Postmarketing Experience
73 **7 DRUG INTERACTIONS**
74 7.1 Subsection Title
75 7.2 Subsection Title
76 **8 USE IN SPECIFIC POPULATIONS**
77 8.1 Pregnancy
78 8.2 Lactation (if not required to be in PLLR format use Labor and Delivery)
79 8.3 Females and Males of Reproductive Potential (if not required to be in PLLR format use Nursing Mothers)
80 8.4 Pediatric Use
81 8.5 Geriatric Use
82 8.8 Subpopulation X
83
84
85

5. Appropriate Page Numbering

This is not page 3,
it is page 1.

NDA 12345: S 123		Confidential
NDA 12345: S 123		Draft 1.38.2A
Page 3 of 55		3/1/2017
1	HIGHLIGHTS OF PRESCRIBING INFORMATION	26
2	These highlights do not include all the information needed to use	27
3	PROPRIETARY NAME safely and effectively. See full prescribing	28
4	information for PROPRIETARY NAME.	29
5		30
6	PROPRIETARY NAME (proprietary name) dosage form, route	31
7	of administration, controlled substance symbol	32
8	INITIAL U.S. Approval: XXXX	33
9		34
	WARNING: TITLE OF WARNING	35
	See full prescribing information for complete boxed warning.	36
	• Text (4)	37
	• Text (5,x)	38
10		39
11	-----RECENT MAJOR CHANGES-----	40
12	Section Title, Subsection Title (x,x) M/YYYY	41
13	Section Title, Subsection Title (x,x) M/YYYY	42
14		43
15	-----INDICATIONS AND USAGE-----	44
16	PROPRIETARY NAME is a (insert FDA established pharmacologic	45
17	class/text phrase) indicated for... (1)	46
18		47
19	Limitations of Use	48
20	Text (1)	49
21		50
22	-----DOSAGE AND ADMINISTRATION-----	51
23		52
24	• Text (2,x)	53
25	• Text (2,x)	54
		55
		56
		57
		58
58	FULL PRESCRIBING INFORMATION: CONTENTS*	
59	WARNING: TITLE OF WARNING	
60	1 INDICATIONS AND USAGE	
61	2 DOSAGE AND ADMINISTRATION	
62	2.1 Subsection Title	
63	2.2 Subsection Title	
64	3 DOSAGE FORMS AND STRENGTHS	
65	4 CONTRAINDICATIONS	
66	5 WARNINGS AND PRECAUTIONS	
67	5.1 Subsection Title	
68	5.2 Subsection Title	
69	6 ADVERSE REACTIONS	
70	6.1 Clinical Trials Experience	
71	6.2 Immunogenicity	
72	6.2 or 6.3 Postmarketing Experience	
73	7 DRUG INTERACTIONS	
74	7.1 Subsection Title	
75	7.2 Subsection Title	
76	8 USE IN SPECIFIC POPULATIONS	
77	8.1 Pregnancy	
78	8.2 Lactation (if not required to be in PLR format use Labor and Delivery)	
79	8.3 Females and Males of Reproductive Potential (if not required to be in PLR format use Nursing Mothers)	
80	8.4 Pediatric Use	
81	8.5 Geriatric Use	
82	8.6 Subpopulation X	
83		
84		
85		

5. Appropriate Page Numbering



First page of the Medication Guide is incorrectly identified as page 38



5. Appropriate Page Numbering

For example, a labeling document with attachments is 40 pages long (30, 5, and 5 pages for PI, MG, and IFU, respectively). Ensure that:

- PI is numbered Pages 1 to 30
- MG is numbered Pages 1 to 5
- IFU is numbered Pages 1 to 5

Updated Optimal Labeling



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol
Initial U.S. Approval: 2016

WARNING: TITLE OF WARNING

See full prescribing information for complete boxed warning.

- Text (4)
- Text (5.x)

RECENT MAJOR CHANGES

Section Title, Subsection Title (x, x) 2/2017
Section Title, Subsection Title (x, x) 4/2017

INDICATIONS AND USAGE

PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for ... (1)

Limitations of Use

Text (1)

DOSAGE AND ADMINISTRATION

- Text (2, x)
- Text (2, x)

DOSAGE FORMS AND STRENGTHS

Dosage form(s); strength(s) (3)

CONTRAINDICATIONS

- Text (4)
- Text (4)

WARNINGS AND PRECAUTIONS

- Text (5, x)
- Text (5, x)

ADVERSE REACTIONS

Most common adverse reactions (incidence > x%) are text (6, x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Text (7, x)
- Text (7, x)

USE IN SPECIFIC POPULATIONS

- Text (8, x)
- Text (8, x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling Q8 and Medication Guide.

Revised: 4/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: TITLE OF WARNING

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Subsection Title

2.2 Subsection Title

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Subsection Title

5.2 Subsection Title

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

6.2 Immunogenicity

6.2 or 6.3 Postmarketing Experience

7 DRUG INTERACTIONS

7.1 Subsection Title

7.2 Subsection Title

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation (if not required to be in PLLR format use Labor and Delivery)

8.3 Females and Males of Reproductive Potential (if not required to be in PLLR format use Nursing Mothers)

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Subpopulation X

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

9.2 Abuse

9.3 Dependence

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

12.4 Microbiology

12.5 Pharmacogenomics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

13.2 Animal Toxicology and/or Pharmacology

14 CLINICAL STUDIES

14.1 Subsection Title

14.2 Subsection Title

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

Resources for Format and Appearance of the Prescribing Information



FDA's Prescription Drug Labeling Resources website provides format resources for the development of Prescribing Information:

<https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources>

- Selected Requirements of Prescribing Information (SRPI) – A 41-item, drop-down checklist of important format elements of the PI based on regulations (21 CFR 201.56 and 201.57) and guidances.
- Sample PLR Template.

Summary



- Lets collaborate together, so we can maintain quality labeling and identify and correct any format issues
 - We are working hard to improve format and appearance issues within CDER.
 - Perform a quality check of labeling prior to approval that includes the following items:
 - Annotations, Line Numbers, Correct Number of Columns, Correct Dates, Appropriate Page Numbering

Thanks!

FDA





U.S. FOOD & DRUG
ADMINISTRATION