

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

LAMOTRIGINE tablets, for oral use

Initial U.S. Approval: 1994

Full prescribing information for complete boxed warning.

- Cases of life-threatening serious rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis, and/or rash-related death have been caused by lamotrigine. The rate of serious rash is greater in pediatric patients than in adults. Additional factors that may increase the risk of rash include:
• concomitant use of valproate,
• exceeding recommended initial dose of lamotrigine,
• exceeding recommended maintenance dose of lamotrigine. (5.1)
• Serious rashes are also caused by lamotrigine; however, it is not possible to predict which rashes will prove to be serious or life-threatening. Lamotrigine should be discontinued at the first sign of rash, unless the rash is clearly not drug related. (5.1)

Warnings and Precautions, Cardiac Rhythm and Conduction Abnormalities (5.4)

Lamotrigine is indicated for:
• Epilepsy—adjunctive therapy in patients aged 2 years and older.
• partial-onset seizures.
• primary generalized tonic-clonic seizures.

Epilepsy—monotherapy in patients aged 16 years and older. Conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug. (1.1)
Bipolar Disorder. Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy. (1.2)
Limitations of Use. Treatment of acute manic or mixed episodes is not recommended. Effectiveness of lamotrigine in the acute treatment of mood episodes has not been established.

• Discontinue concomitant medications, including partial-onset seizures, to avoid an increased risk of rash, the recommended initial dose and subsequent dose escalations should not be exceeded. (2.1, 16)
• Do not restart lamotrigine in patients who discontinued due to rash unless the potential benefits clearly outweigh the risks. (2.1, 5.1)
• Adjustments to maintenance doses will be necessary in most patients starting or stopping lamotrigine. (2.1, 5.1)
• Discontinuation. Taper over a period of at least 2 weeks (approximately 50% dose reduction per week). (2.1, 5.1)
• Pregnancy. See Table 1 for patients older than 12 years and Tables 2 and 3 for patients aged 2 to 12 years. (2.2)
• Conversion to monotherapy—See Table 4. (2.3)

Full Prescribing Information: Contents\*

WARNING: SERIOUS SKIN RASHES

1. INDICATIONS AND USAGE

2. DOSAGE AND ADMINISTRATION

3. DOSAGE FORMS AND STRENGTHS

4. CONTRAINDICATIONS

5. WARNINGS AND PRECAUTIONS

6. ADVERSE REACTIONS

7. DRUG INTERACTIONS

8. USE IN SPECIFIC POPULATIONS

9. OVERDOSAGE

10. CLINICAL PHARMACOLOGY

11. NONCLINICAL TOXICOLOGY

12. HOW SUPPLIED/STORAGE AND HANDLING

13. PATIENT COUNSELING INFORMATION

14. CLINICAL STUDIES

15. REFERENCES

16. HOW SUPPLIED/STORAGE AND HANDLING

17. PATIENT COUNSELING INFORMATION

18. CLINICAL STUDIES

19. REFERENCES

20. HOW SUPPLIED/STORAGE AND HANDLING

21. PATIENT COUNSELING INFORMATION

22. CLINICAL STUDIES

23. REFERENCES

24. HOW SUPPLIED/STORAGE AND HANDLING

25. PATIENT COUNSELING INFORMATION

26. CLINICAL STUDIES

27. REFERENCES

28. HOW SUPPLIED/STORAGE AND HANDLING

29. PATIENT COUNSELING INFORMATION

30. CLINICAL STUDIES

31. REFERENCES

32. HOW SUPPLIED/STORAGE AND HANDLING

33. PATIENT COUNSELING INFORMATION

34. CLINICAL STUDIES

35. REFERENCES

36. HOW SUPPLIED/STORAGE AND HANDLING

37. PATIENT COUNSELING INFORMATION

38. CLINICAL STUDIES

39. REFERENCES

40. HOW SUPPLIED/STORAGE AND HANDLING

41. PATIENT COUNSELING INFORMATION

42. CLINICAL STUDIES

43. REFERENCES

44. HOW SUPPLIED/STORAGE AND HANDLING

45. PATIENT COUNSELING INFORMATION

46. CLINICAL STUDIES

47. REFERENCES

48. HOW SUPPLIED/STORAGE AND HANDLING

49. PATIENT COUNSELING INFORMATION

50. CLINICAL STUDIES

51. REFERENCES

52. HOW SUPPLIED/STORAGE AND HANDLING

53. PATIENT COUNSELING INFORMATION

54. CLINICAL STUDIES

55. REFERENCES

56. HOW SUPPLIED/STORAGE AND HANDLING

57. PATIENT COUNSELING INFORMATION

58. CLINICAL STUDIES

59. REFERENCES

60. HOW SUPPLIED/STORAGE AND HANDLING

61. PATIENT COUNSELING INFORMATION

62. CLINICAL STUDIES

63. REFERENCES

64. HOW SUPPLIED/STORAGE AND HANDLING

65. PATIENT COUNSELING INFORMATION

66. CLINICAL STUDIES

67. REFERENCES

68. HOW SUPPLIED/STORAGE AND HANDLING

69. PATIENT COUNSELING INFORMATION

70. CLINICAL STUDIES

71. REFERENCES

72. HOW SUPPLIED/STORAGE AND HANDLING

73. PATIENT COUNSELING INFORMATION

74. CLINICAL STUDIES

75. REFERENCES

76. HOW SUPPLIED/STORAGE AND HANDLING

77. PATIENT COUNSELING INFORMATION

78. CLINICAL STUDIES

79. REFERENCES

80. HOW SUPPLIED/STORAGE AND HANDLING

81. PATIENT COUNSELING INFORMATION

82. CLINICAL STUDIES

83. REFERENCES

84. HOW SUPPLIED/STORAGE AND HANDLING

85. PATIENT COUNSELING INFORMATION

86. CLINICAL STUDIES

87. REFERENCES

88. HOW SUPPLIED/STORAGE AND HANDLING

89. PATIENT COUNSELING INFORMATION

90. CLINICAL STUDIES

91. REFERENCES

92. HOW SUPPLIED/STORAGE AND HANDLING

93. PATIENT COUNSELING INFORMATION

94. CLINICAL STUDIES

95. REFERENCES

96. HOW SUPPLIED/STORAGE AND HANDLING

97. PATIENT COUNSELING INFORMATION

98. CLINICAL STUDIES

99. REFERENCES

100. HOW SUPPLIED/STORAGE AND HANDLING

101. PATIENT COUNSELING INFORMATION

102. CLINICAL STUDIES

103. REFERENCES

104. HOW SUPPLIED/STORAGE AND HANDLING

105. PATIENT COUNSELING INFORMATION

106. CLINICAL STUDIES

107. REFERENCES

108. HOW SUPPLIED/STORAGE AND HANDLING

109. PATIENT COUNSELING INFORMATION

110. CLINICAL STUDIES

111. REFERENCES

112. HOW SUPPLIED/STORAGE AND HANDLING

113. PATIENT COUNSELING INFORMATION

114. CLINICAL STUDIES

115. REFERENCES

116. HOW SUPPLIED/STORAGE AND HANDLING

117. PATIENT COUNSELING INFORMATION

118. CLINICAL STUDIES

119. REFERENCES

120. HOW SUPPLIED/STORAGE AND HANDLING

121. PATIENT COUNSELING INFORMATION

122. CLINICAL STUDIES

123. REFERENCES

124. HOW SUPPLIED/STORAGE AND HANDLING

125. PATIENT COUNSELING INFORMATION

126. CLINICAL STUDIES

127. REFERENCES

128. HOW SUPPLIED/STORAGE AND HANDLING

129. PATIENT COUNSELING INFORMATION

130. CLINICAL STUDIES

131. REFERENCES

132. HOW SUPPLIED/STORAGE AND HANDLING

133. PATIENT COUNSELING INFORMATION

134. CLINICAL STUDIES

135. REFERENCES

136. HOW SUPPLIED/STORAGE AND HANDLING

137. PATIENT COUNSELING INFORMATION

138. CLINICAL STUDIES

139. REFERENCES

140. HOW SUPPLIED/STORAGE AND HANDLING

141. PATIENT COUNSELING INFORMATION

142. CLINICAL STUDIES

143. REFERENCES

144. HOW SUPPLIED/STORAGE AND HANDLING

145. PATIENT COUNSELING INFORMATION

146. CLINICAL STUDIES

147. REFERENCES

148. HOW SUPPLIED/STORAGE AND HANDLING

149. PATIENT COUNSELING INFORMATION

150. CLINICAL STUDIES

151. REFERENCES

152. HOW SUPPLIED/STORAGE AND HANDLING

153. PATIENT COUNSELING INFORMATION

154. CLINICAL STUDIES

155. REFERENCES

156. HOW SUPPLIED/STORAGE AND HANDLING

157. PATIENT COUNSELING INFORMATION

158. CLINICAL STUDIES

159. REFERENCES

160. HOW SUPPLIED/STORAGE AND HANDLING

161. PATIENT COUNSELING INFORMATION

162. CLINICAL STUDIES

163. REFERENCES

164. HOW SUPPLIED/STORAGE AND HANDLING

165. PATIENT COUNSELING INFORMATION

166. CLINICAL STUDIES

167. REFERENCES

168. HOW SUPPLIED/STORAGE AND HANDLING

169. PATIENT COUNSELING INFORMATION

170. CLINICAL STUDIES

171. REFERENCES

172. HOW SUPPLIED/STORAGE AND HANDLING

173. PATIENT COUNSELING INFORMATION

174. CLINICAL STUDIES

175. REFERENCES

176. HOW SUPPLIED/STORAGE AND HANDLING

177. PATIENT COUNSELING INFORMATION

178. CLINICAL STUDIES

179. REFERENCES

180. HOW SUPPLIED/STORAGE AND HANDLING

181. PATIENT COUNSELING INFORMATION

182. CLINICAL STUDIES

183. REFERENCES

184. HOW SUPPLIED/STORAGE AND HANDLING

185. PATIENT COUNSELING INFORMATION

186. CLINICAL STUDIES

187. REFERENCES

188. HOW SUPPLIED/STORAGE AND HANDLING

189. PATIENT COUNSELING INFORMATION

190. CLINICAL STUDIES

191. REFERENCES

192. HOW SUPPLIED/STORAGE AND HANDLING

193. PATIENT COUNSELING INFORMATION

194. CLINICAL STUDIES

195. REFERENCES

196. HOW SUPPLIED/STORAGE AND HANDLING

197. PATIENT COUNSELING INFORMATION

198. CLINICAL STUDIES

199. REFERENCES

200. HOW SUPPLIED/STORAGE AND HANDLING

201. PATIENT COUNSELING INFORMATION

202. CLINICAL STUDIES

203. REFERENCES

204. HOW SUPPLIED/STORAGE AND HANDLING

205. PATIENT COUNSELING INFORMATION

206. CLINICAL STUDIES

207. REFERENCES

208. HOW SUPPLIED/STORAGE AND HANDLING

209. PATIENT COUNSELING INFORMATION

210. CLINICAL STUDIES

211. REFERENCES

212. HOW SUPPLIED/STORAGE AND HANDLING

213. PATIENT COUNSELING INFORMATION

214. CLINICAL STUDIES

215. REFERENCES

216. HOW SUPPLIED/STORAGE AND HANDLING

217. PATIENT COUNSELING INFORMATION

218. CLINICAL STUDIES

219. REFERENCES

220. HOW SUPPLIED/STORAGE AND HANDLING

221. PATIENT COUNSELING INFORMATION

222. CLINICAL STUDIES

223. REFERENCES

224. HOW SUPPLIED/STORAGE AND HANDLING

225. PATIENT COUNSELING INFORMATION

226. CLINICAL STUDIES

227. REFERENCES

228. HOW SUPPLIED/STORAGE AND HANDLING

229. PATIENT COUNSELING INFORMATION

230. CLINICAL STUDIES

231. REFERENCES

232. HOW SUPPLIED/STORAGE AND HANDLING

233. PATIENT COUNSELING INFORMATION

234. CLINICAL STUDIES

235. REFERENCES

236. HOW SUPPLIED/STORAGE AND HANDLING

237. PATIENT COUNSELING INFORMATION

238. CLINICAL STUDIES

239. REFERENCES

240. HOW SUPPLIED/STORAGE AND HANDLING

241. PATIENT COUNSELING INFORMATION

242. CLINICAL STUDIES

243. REFERENCES

244. HOW SUPPLIED/STORAGE AND HANDLING

245. PATIENT COUNSELING INFORMATION

246. CLINICAL STUDIES

247. REFERENCES

248. HOW SUPPLIED/STORAGE AND HANDLING

249. PATIENT COUNSELING INFORMATION

250. CLINICAL STUDIES

251. REFERENCES

252. HOW SUPPLIED/STORAGE AND HANDLING

253. PATIENT COUNSELING INFORMATION

254. CLINICAL STUDIES





## **JOB SPECIFICATION FORM**

**Customer Name:**

**Artwork #:**

**Customer Rep:**

**Date Submitted:**

---

### **JOB INFO**

**Job Name:**

**Type: New Design ( )**

**Reprint ( )**

**File Name:**

**JOB TYPE: ( ) Insert**

**( ) Med Guide**

**( ) Patient Guide**

**Rev:**

**Proof #:**

**Grain direction:**

**Manufacture by:**

**Manufacture for:**

**Fold Type:**

**Flat Size:**

**Final Folded size:**

**Finishing For Padding:**

**Customer Item #:**

**Barcode Reader:**

**Barcode Type:**

**Paper Stock:**

**Ink:**

---

**Notes**

---

**APPROVED: OK to Print ( ) DATE:**

**Approved By:**

**DATE OF APPROVAL:**

**\* Please review in detail for Layout, Content, Spelling, Spacing, Grammar, Structures, Colors, Barcode and all Specs related to this Artwork.**

**MedLit Graphics Inc. is not responsible for errors on printed product that appear on this proof.**