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U.S. Food and Drug Administration



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Drug Details

Drug Name(s)

LAMICTAL (Brand Name Drug)

FDA Application No. (NDA) 020241

Active Ingredient(s)

LAMOTRIGINE

Company GLAXOSMITHKLINE

Original Approval or Tentative Approval Date December 27, 1994

Chemical Type 1 New molecular entity (NME)

Review Classification P Priority review drug

- Therapeutic Equivalents
- Approval History, Letters, Reviews, and Related Documents
- Dear Health Professional Letter

- Label Information
- Dear Health Professional Letter
- Other Important Information from FDA

Products on Application (NDA) #020241

Click on a column header to re-sort the table:

Drug Name	Active Ingredients	<u>Strength</u>	Dosage Form/Route	Marketing Status	RLD	TE Code
LAMICTAL	LAMOTRIGINE	100MG	TABLET; ORAL	Prescription	No	AB
LAMICTAL	LAMOTRIGINE	150MG	TABLET; ORAL	Prescription	No	AB

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LAMICTAL	LAMOTRIGINE	200MG	TABLET; ORAL	Prescription	No	AB
LAMICTAL	LAMOTRIGINE	250MG	TABLET; ORAL	Discontinued	No	None
LAMICTAL	LAMOTRIGINE	25MG	TABLET; ORAL	Prescription	Yes	AB
LAMICTAL	LAMOTRIGINE	50MG	TABLET; ORAL	Discontinued	No	None

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