EXHIBIT L

Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 020229
Company: JANSSEN PHARMS

Products on NDA 020229

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
LEUSTATIN	CLADRIBINE	1MG/ML **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	INJECTABLE;INJECTION	Discontinued	None	Yes	No

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020229

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
02/26/1993	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD		Withdrawn FR Effective 11/03/2016 Label is not available on this site.

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
08/02/2012	SUPPL-34		Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/
06/29/2006	SUPPL-30		Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
08/22/2002	SUPPL-21		Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/
08/20/2002	SUPPL-7		Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/
08/20/2002	SUPPL-4		Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/

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Labels for NDA 020229

LEUSTATIN® (cladribine)
Injection
For Intravenous Infusion Only

WARNING

LEUSTATIN (cladribine) Injection should be administered under the supervision of a qualified physician experienced in the use of antineoplastic therapy. Suppression of bone marrow function should be anticipated. This is usually reversible and appears to be dose dependent. Serious neurological toxicity (including irreversible paraparesis and quadraparesis) has been reported in patients who received LEUSTATIN Injection by continuous infusion at high doses (4 to 9 times the recommended dose for Hairy Cell Leukemia). Neurologic toxicity appears to demonstrate a dose relationship; however, severe neurological toxicity has been reported rarely following treatment with standard cladribine dosing regimens.

Acute nephrotoxicity has been observed with high doses of LEUSTATIN (4 to 9 times the recommended dose for Hairy Cell Leukemia), especially when given concomitantly with other nephrotoxic agents/therapies.

DESCRIPTION

LEUSTATIN (cladribine) Injection (also commonly known as 2-chloro-2′-deoxy-β-D-adenosine) is a synthetic antineoplastic agent for continuous intravenous infusion. It is a clear, colorless, sterile, preservative-free, isotonic solution. LEUSTATIN Injection is available in single-use vials containing 10 mg (1 mg/mL) of cladribine, a chlorinated purine nucleoside analog. Each milliliter of LEUSTATIN Injection contains 1 mg of the active ingredient and 9 mg (0.15 mEq) of sodium chloride as an inactive ingredient. The solution has a pH range of 5.5 to 8.0. Phosphoric acid and/or dibasic sodium phosphate may have been added to adjust the pH to 6.3±0.3.

The chemical name for cladribine is 2-chloro-6-amino-9-(2-deoxy-β-D-erythropento-furanosyl) purine and the structure is represented below:

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