Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 020573
Company: HORIZON PHARMA INC

Products on NDA 020573

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
BUPHENYL	SODIUM PHENYLBUTYRATE	3GM/TEASPOONFUL	POWDER;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020573

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
04/30/1996	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY; Orphan		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
08/05/2013	SUPPL-19	Manufacturing (CMC)	
03/31/2009	SUPPL-15	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020572s016,020573s015lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/020572s016,020573s015ltr.pdf)**
10/09/1998	SUPPL-2	Labeling	
11/07/1996	SUPPL-1	Manufacturing (CMC)-Control	

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Labels for NDA 020573

Therapeutic Equivalents for NDA 020573