

Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 020573

Company: HORIZON PHARMA INC

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Products on NDA 020573

CSV Excel Print

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

Showing 1 to 1 of 1 entries

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.

Showing 1 to 1 of 1 entries

Supplements

CSV	Excel	Print		
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/applletter/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](#)
