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Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 022233
Company: HELSINN HLTHCARE

[EMAIL \(MAILTO:SUBJECT=DRUGS@FDA&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VA\)](mailto:SUBJECT=DRUGS@FDA&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VA)

- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/022233s000Sumr.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/022233s000Sumr.pdf)

Products on NDA 022233

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
ALOXI	PALONOSETRON HYDROCHLORIDE	EQ 0.5MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	CAPSULE;ORAL	Discontinued	None	Yes	No

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022233

Labels for NDA 022233

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/01/2020	SUPPL-6	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022233s006lbl.pdf)	
09/18/2014	SUPPL-5	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022233s005lbl.pdf)	
08/22/2008	ORIG-1	Approval	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022233LBL.pdf)	

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