Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 020645
Company: MEDICIS

- Label as it appears on Package (http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020645_box_lbl.pdf)

Products on NDA 020645

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
AMMONUL	SODIUM BENZOATE; SODIUM PHENYLACETATE	10%;10% (5GM/50ML;5GM/50ML)	SOLUTION;INTRAVENOUS	Prescription	AP	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020645

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
02/17/2005	ORIG-1	Approval	Type 3 - New Dosage Form	PRIORITY	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/lab Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/200

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
01/10/2017	SUPPL-10	Manufacturing (CMC)		Label is not available on this site.
08/07/2013	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
06/30/2011	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020645s008lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020645s008ltr.pdf)**	

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Labels for NDA 020645

Therapeutic Equivalents for NDA 020645