DOCUSATE SODIUM- docusate sodium tablet
Olds Softgels Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Docusate Sodium 50%

IMPORTANT

This is a bulk shipment, intended for further processing only. It is not to be used in its present condition and it should be repackaged immediately and labeled strictly in conformance with the Federal Food, Drug and Cosmetic Act and other pertinent government regulations.

Keep out of reach of children.

Olds SoftGels Inc

All complaints or claims for allowances of any kind must be made within 10 days after receipt of goods.

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INGREDIENTS: docusate sodium 50% in PEG 400 FD&C red #40 granular, FD&C yellow #6 granular, gelatin, glycerin, polyethylene glycol 400 USP (PEG 400) propylene glycol, purified water, sorbitol special GC

DOCUSATE SODIUM

docusate sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69160-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	401
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69160-002-01	18000 in 1 BOX; Type 0: Not a Combination Product	05/19/2015	
2	NDC:69160-002-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/19/2015	

Labeler - Olds Softgels Inc. (202822235)

Establishment

Name	Address	ID/FEI	Business Operations
Olds Softgels Inc.		202822235	manufacture(69160-002) , label(69160-002) , pack(69160-002)