DOCUSATE SODIUM 250MG- docusate sodium capsule
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.

ACTIVE INGREDIENT

Docusate Sodium 250 mg

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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INACTIVE INGREDIENTS

Red No. 40

Granular FD and C

Yellow No.6

Granular

Gelatin

Glycerin USP 99 Percent

Polyethylene

Glycol 400 USP PEG 400

Propylene glycol

Purified water

Sorbitol special GC

PACKAGE LABEL

DOCUSATE SODIUM 250MG

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69160-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 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	red (40) , yellow (6)	**Score**	no score
Shape	OVAL	**Size**	23mm
Flavor		**Imprint Code**	GC425
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69160-003-01	7000 in 1 BOX; Type 0: Not a Combination Product	05/18/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/18/2016	

Labeler - Olds Softgels Inc. (202822235)

Establishment

Name	Address	ID/FEI	Business Operations

Olds Softgels Inc.		202822235	manufacture(69160-003)