DOCUSATE SODIUM- docusate sodium capsule
DirectRX

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

Docusate Sodium 100 mg

Stool softener laxative

relieves occasional constipation (irregularity)
generally produces bowel movement in 12 to 72 hours

Do not use

if you are presently taking mineral oil, unless told to do so by a doctor.

Ask a doctor before use if you have

stomach pain
nausea
vomiting
noticed a sudden change in bowel habits that last over 2 weeks

Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be a signs of a serious condition.
you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over take 1 to 3 softgels daily.
children 2 to under 12 years of age take 1 softgel daily
children under 2 years ask a doctor

each softgel contains: sodium 6 mg
store at 25ºC (77ºF);excursions permitted between 15-30ºC (59-86ºF)

edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water sorbitan, sorbitol

*contains one or more of these ingredients

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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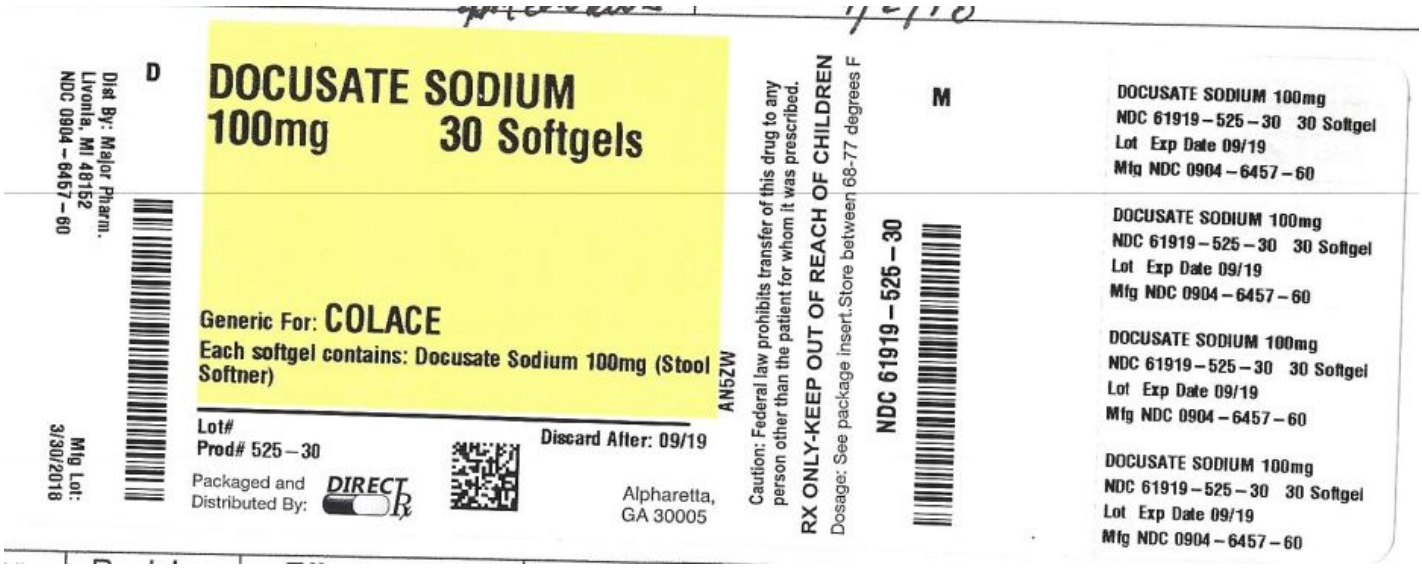

DOCUSATE SODIUM

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-525(NDC:0904-6457)
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**
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SORBITAN (UNII: 6O92ICV9RU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	P51;S77;SCU1;D2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-525-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/24/2019	

Labeler - DirectRX (079254320)

Registrant - DirectRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DirectRX		079254320	repack(61919-525)

Revised: 4/2019 DirectRX