DOK- dok capsule RedPharm Drug, 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

ACTIVE INGREDIENT (IN EACH SOFTGEL)

Docusate Sodium 100 mg

PURPOSE

Stool softener laxative

USES

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

WARNINGS

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.

DIRECTIONS

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

OTHER INFORMATION

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

INACTIVE INGREDIENTS

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

QUESTIONS OR COMMENTS?

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

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

PRINCIPAL DISPLAY PANEL

NDC: 67296-1556-2 DOCUSATE SODIUM 20 Softgels Exp: 04/20

Rx Only

Lot: A55467 2

Usual adult dosage: See package insert Store at controlled room temperature: 25 C (77 F)

Mfg For Major Pharmaceuticals
Livonia, MI 48152
0904-6457-80
Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN 207531





Rx Only

60 Softgels

Exp: 04/20

Usual adult dosage: See package insert Store at controlled room temperature: 25 C (77 F)

Mfg For: Major Pharmaceuticals Livonia, MI 48152 0904-6457-80 Dist. by: Redpharm Drug Eden Prairie. MN 55344

SIN 207530



dok capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1556(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		
SORBITOL (UNII: 506T60A25R)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
SORBITAN (UNII: 6O92ICV9RU)			
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
WATER (UNII: 059QF0KO0R)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			

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

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:67296-1556-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 18	
	2 NDC:67296-1556-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 18	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	0 1/0 1/20 18	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment				
Name	Address	ID/FEI	Business Operations	
RedPharm Drug, Inc.		828374897	repack(67296-1556), relabel(67296-1556)	

Revised: 1/2018 RedPharm Drug, Inc.