DOK- docusate sodium capsule, liquid filled Cardinal Health

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.

Major 44-655

Active ingredient (in each liquid-filled capsule)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Very low Sodium

Each capsules contains: sodium 6 mg

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 lasts 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 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 (1-800-222-1222) right away.

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only.

Directions

- take with a glass of water
- 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 capsules daily	
children 2 to under 12 years of age	take 1 capsule daily	
children under 2 years of age	ask a doctor	

Other information

- each capsule contains: sodium 6 mg Very Low Sodium
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from excessive humidity
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- see end flap for expiration date and lot number

Questions or comments?

(800) 616-2471

Inactive ingredients

citric acid, edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, propylene glycol, purified water, sorbitol

Distributed by MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA

Product of China

Packaged and Quality Assured in the USA

MFGD By PuraCap Pharm., LLC NJ 07080

Distributed by:

Cardinal Health

Dublin, OH 43017

L51685130218

Principal Display Panel

DOK 100 mg

Docusate Sodium

10 Softgels



H98

DOK 100 mg Docusate Sodium

10 SOFTGELS

Stool Softener Laxative

Very Low Sodium

each capsule contains: sodium 6 mg

Drug Facts

Active ingredient (in each liquid-filled capsule)

Purpose

Docusate sodium 100 mg

Stool softener laxative

Uses - relieves occasional constipation (irregularity)

- generally produces bowel movement in 12 to 72 hours

Directions - take with a glass of water

- 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 capsules daily children 2 to under 12 years of age take 1 capsule daily children under 2 years of age ask a doctor

STORAGE: Store at 25° C (77° F); excursions permitted between 15° - 30° C (59° - 86° F) - protect from excessive humidity

Inactive ingredients citric acid, edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, propylene glycol, purified water, sorbitol

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 lasts 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 signs of a serious condition.

you need to use a laxative for more than 1 week

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. 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 (1-800-222-1222) right away.

TAMPER EVIDENT: DO NOT USE IF BLISTER IS TORN OR BROKEN

Distributed by MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA

Product of China

Packaged and Quality Assured in the USA Questions or comments? (800) 616-2471 MFGD By PuraCap Pharm., LLC NJ 07080

Distributed by Cardinal Health

Dublin, OH 43017 L51685130218

LOT #: XXXXXXXXXX EXP. DATE: XX/XX/XX

DOK

docusate sodium capsule, liquid filled

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:55154-7636(NDC:0904-6455)Route of AdministrationORAL

Active Ingredient/Active Moiety

3		
Ingredient Name	Basis of Strength	Strength
DO CUSATE SO DIUM (UNII: F05Q2T2JA0) (DO CUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
MINERAL OIL (UNII: T5L8T28FGP)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	ORANGE	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	655
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55154-7636-0	10 in 1 BAG	03/01/2015	
1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	0 3/0 1/20 15	

Labeler - Cardinal Health (603638201)

Revised: 9/2018 Cardinal Health