

DOK- docusate sodium capsule

Major Pharmaceuticals

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.

Drug Facts

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

Principal Display Panel

Compare to the active ingredient in Colace® Regular Strength Stool Softener**

DOK™ 100 mg

Docusate sodium

Stool Softener Laxative

For Use as a Stool Softener in Treating & Avoiding Constipation

Softgels

**This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® Regular Strength Stool Softener.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed by:

Major® Pharmaceuticals

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Product Label

MAJOR® NDC 0904-6457-60

Compare to the active ingredient in Colace® Regular Strength Stool Softener**

DOK™ 100 mg
Docusate sodium

Stool Softener Laxative

For Use as a Stool Softener in Treating & Avoiding Constipation

100 Softgels



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Drug Facts (continued under label)

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Distributed by:

Major® Pharmaceuticals

17177 N Laurel Park Drive, Suite 233 M-58 Rev 10/17
Livonia, MI 48152 Re-Order No. 700370



PLD-E11
LB0051069

Lot No.:

Exp. Date:

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Drug Facts (continued)

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MAJOR Stool Softener Laxative

DOK

docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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 RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
SORBITAN (UNII: 6O92ICV9RU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

SORBITOL (UNII: 506T60A25R)

GLYCERIN (UNII: PDC6A3C0OX)

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:0904-6457-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2015	
2	NDC:0904-6457-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	02/28/2015	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2019

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