

**DOK EXTRA STRENGTH STOOL SOFTENER- docusate sodium capsule, liquid filled  
H.J. Harkins Company, 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.*

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**Drug Facts**

**Active ingredient (in each softgel)**

Docusate Sodium 250mg

**Purpose**

Stool softener

**Uses**

- for the prevention of dry, hard stools
- for relief of occasional constipation.
- this product generally produces a bowel movement within 12 to 72 hours.

**Warnings - Do not use**

- if you are taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for more than 1 week, unless directed by a doctor

**Ask a doctor before use if**

you notice a sudden change in bowel habits that persists over a period of 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding
- you fail to have a bowel movement after use

**If pregnant or breastfeeding**

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**

- **adults and children over 12 years of age and over:** take 1 softgel daily or as directed by a doctor
- **children under 12 years of age:** take as directed by a doctor

**Other information**

- **each softgel contains** sodium 15mg
- store at controlled room temperature 15° - 30° C (59°- 86° F)
- do not use if imprinted safety seal under cap is broken or missing

## Inactive Ingredients

edible white ink, FD&C Red No# 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified wter, sorbitol special.

## Questions or comments?

Adverse Drug Event Call: **(800) 616-2471**

## Product Labeling

### MAJOR DOK™

Docusate Sodium 250 mg

Extra Strength Stool Softener

For use as a Stool Softener in treating & Avoiding Constipation

Distributed by:

### Major Pharmaceuticals

31778 Enterprise Drive

Livonia, MI 48150, USA

Repacked by:

H.J. Harkins Company, Inc.

Grover Beach, CA 93433

**76519-1003-6**

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info  
KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place at 68 to 77 degrees F.

**DOCUSATE SODIUM 250mg SOFTGELS**

Lot #: DSS202M	<b>#60</b>
Mfg: MAJOR	
Exp: 01/14	Compare to: Colace
Mfg. Livonia,	Mfg. NDC: 0904-7891-59
Loc: MI	Pill ID: Orange capsule.

Take as directed by your Doctor or  
See outsert for usual dosage information

DOCUSATE SODIUM 250mg SOFTGELS		
76519-1003-6	Qty	#60
01/14	Lot	DSS202M
Colace		0904-7891-59

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01/14	Lot	DSS202M
Colace		0904-7891-59

Repack: H.J. Harkins Co., Inc. Grover Beach, CA 93433  
Dispense in tight, child & light-resistant container per USP

**Docusate Sodium 250 mg**

## DOK EXTRA STRENGTH STOOL SOFTENER

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76519-1003(NDC:0904-7891)	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE SODIUM	250 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
<b>Product Characteristics</b>				
<b>Color</b>	ORANGE (orange)	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm	
<b>Flavor</b>		<b>Imprint Code</b>	P20	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76519-1003-6	60 in 1 BOTTLE, PLASTIC		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC MONOGRAPH NOT FINAL	part334	08/27/2002		

**Labeler** - H.J. Harkins Company, Inc. (147681894)

**Registrant** - H.J. Harkins Company, Inc. (147681894)

### Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	repack(76519-1003) , relabel(76519-1003)

