

**DOCUSATE SODIUM- docusate sodium capsule, liquid filled**  
**J.P. BUSINESS ENTERPRISE**

*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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**DOCUSATE SODIUM SOFTGEL CAPSULES 100MG**

***Drug Facts***

**Active ingredient (in each softgel)**

Docusate sodium 100 mg

**Purpose**

Stool softener

**Uses**

- for 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 currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for longer 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 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 with a glass of water

adults and children 12 years of age and over	take 1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses.
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years of age	consult a physician

**Other information**

- **each softgel contains:** sodium 6 mg
- 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**

FD&C Red # 40, FD&C Yellow #6, gelatin, glycerine, polyethylene glycol 400, propylene glycol, purified water, sorbitol solution, titanium dioxide (for printing)

**Questions or comments?**

Call toll free: **1-888-333-9792**

Distributed By: J.P Business Enterprise  
Lake Grove, NY 11755

**PRINCIPAL DISPLAY PANEL - 50 Softgel Bottle Carton****VALUMEDS**

Compare to the active ingredient in  
**Dulcolax® Stool Softener**

**STOOL SOFTENER****DOCUSATE SODIUM 100 MG**

- GENTLE RELIEF
- EFFECTIVE
- STIMULANT FREE

**50 SOFTGELS**

SAVE BOX FOR COMPLETE DRUG FACTS

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Compare to the active ingredient in Dulcolax® Stool Softener

# STOOL SOFTENER

## DOCUSATE SODIUM 100 MG

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50 SOFTGELS



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# STOOL SOFTENER

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**Drug Facts (continued)**

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



0 40232 00474 2

LOT:  
EXP:

ORIG 2/14

\*This product is not manufactured or distributed by Boehringer Ingelheim Consumer Healthcare, owner of the registered trademark Dulcolax®

## DOCUSATE SODIUM

docusate sodium capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59 105-007
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	125
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59 105-007-50	1 in 1 CARTON	12/01/2014	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<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	12/01/2014	

**Labeler** - J.P. BUSINESS ENTERPRISE (078775890)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
MEDGEL PVT LTD		677385498	manufacture(59 105-007)

