

**STOOL SOFTENER- docusate sodium capsule, liquid filled
WALGREEN CO.**

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.

Walgreens 44-351 Delisted

Active ingredient (in each liquid gel)

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 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.

Directions

- take only by mouth. Doses may be taken as a single daily dose or in divided doses.
- take with a glass of water

adults and children take 1 to 3 liquid gels

12 years and over daily

children 2 to under

children 2 to under 12 years of age take 1 liquid gel daily
children under 2 years of age ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from excessive humidity
- use by expiration date on package

Inactive ingredients

D&C yellow #10, edible white ink, FD&C red #40, gelatin, glycerine, polyethylene glycol, propylene glycol, sorbitol

Questions or comments?

1-800-426-9391

Principal display panel

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED

NDC 0363-0351-56

STOOL SOFTENER

Gentle

Laxative

Docosate Sodium USP 100 mg

- Gentle & easy relief of occasional constipation

25

LIQUID GELS

Compare to Dulcolax® Stool Softener Liquid Gels active ingredient

Walgreens Pharmacist Survey Study, November 2012.

This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., owner of the registered trademark Dulcolax® Stool Softener Liquid Gels.

50844 REV0712B35156

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



Gentle & easy relief of occasional constipation.

ORG0612_R01

STOOL SOFTENER

Gentle Laxative



WALGREENS PHARMACIST RECOMMENDED*

Docosate Sodium USP 100 mg

• Gentle & easy relief of occasional constipation

25 LIQUID GELS



Actual Size*

Compare to Dulcolax® Stool Softener Liquid Gels active ingredient**

NDC 0360-0391-56

8313581

LEB0632K

*Walgreens Pharmacist Survey Study, November 2010. **This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., owner of the registered trademark Dulcolax® Stool Softener Liquid Gels.

Drug Facts (continued)

Other information
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
 ■ protect from excessive humidity
 ■ see end flap for expiration date and lot number

Inactive ingredients D&C yellow #10, edible white ink, FD&C red #40, gelatin, glycerine, polyethylene glycol, propylene glycol, sorbitol

Questions or comments? 1-800-426-9391



B-2201-351-56-R
 REV0712B35156

OMIT A

50844 REV0712B35156

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PRODUCT OF CANADA

Drug Facts

Active ingredient (in each liquid gel) Docosate sodium 100 mg

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 Ask a doctor before use if you have
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 Stop use and ask a doctor if
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 ■ you need to use a laxative for more than 1 week
 If pregnant or breast-feeding, ask a health professional before use.
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 adults and children 12 years and over take 1 to 3 liquid gels daily
 children 2 to under 12 years of age take 1 liquid gel daily
 children under 2 years of age ask a doctor

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

ITEM 560140
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Walgreens 44-351

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0351
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
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	RED	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	A92
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0351-56	1 in 1 CARTON		
1		25 in 1 BOTTLE; 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	09/21/1995	07/27/2018

Labeler - WALGREEN CO. (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries, Ltd.		248441727	MANUFACTURE(0363-0351)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0351)

Revised: 7/2015

WALGREEN CO.