

## **DOCUSATE SODIUM- docusate sodium capsule, liquid filled**

### **American Health Packaging**

*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, USP**

### **Stool Softener Laxative**

#### ***Drug Facts***

#### ***Active ingredient (in each softgel)***

Docusate Sodium 100 mg

#### ***Purpose***

Stool softener laxative

#### ***Uses***

- for relief of occasional constipation (irregularity)
- 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 unless directed by a doctor
- for longer than one 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 or you fail to have a bowel movement after use of a laxative. This may indicate a serious condition.

**If pregnant or breast-feeding**, ask a health care 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 of age and over	take 1 to 3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years of age	ask a doctor

#### ***Other information***

- **Each softgel contains:** sodium 7 mg VERY LOW SODIUM
- Store at room temperature between 15° to 30°C (59° to 86°F)

- **FOR YOUR PROTECTION:** Do not use if blister is torn or broken.

***Inactive ingredients***

FD&C Red #40, FD&C Yellow #6, Gelatin USP, Glycerin USP, Polyethylene Glycol 400 NF, Purified Water USP, Sorbital USP

The drug product contained in this package is from NDC # 61301-8001, SWISSCAPS Romania srl.

Distributed by:

American Health Packaging  
2550 John Glenn Avenue, Suite A  
Columbus, OH 43217

712901

0412901/0216PS

**Principal Display Panel – Carton – 100 mg**

NDC 60687-129-01

DOCUSATE SODIUM, USP Stool Softener Laxative

100 mg

100 Softgels (10 x 10)



(01) 0 03 60687 129 01 3

**Drug Facts**

Active ingredient (in each softgel)	Purpose
Docosate Sodium 100 mg	Stool softener laxative

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**Warnings Do not use** ■ if you are currently taking mineral oil, unless directed by a doctor ■ when abdominal pain, nausea or vomiting are present unless directed by a doctor ■ for longer than one week unless directed by a doctor

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NDC 60687-129-01

DOCUSATE SODIUM, USP

Stool Softener Laxative

100 mg

100 Softgels (10 x 10)

**Drug Facts (continued)**

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The drug product contained in this package is from NDC # 61301-8001, SWISSCAPS Romania srl.

Packaged and Distributed by:  
American Health Packaging  
Columbus, Ohio 43217

712901  
0412901/0119

NDC 60687- 129-01

DOCUSATE SODIUM, USP

Stool Softener Laxative

**100 mg**


**100 Softgels (10 x 10)**

The drug product contained in this package is from  
NDC # 61301-8001, SWISSCAPS Romania srl.


Packaged and Distributed by:  
American Health Packaging  
Columbus, OH 43217

712901  
0412901/0119


**Principal Display Panel - Blister – 100 mg**

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**  
  
(01) 003 60687 129 11 2  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

DOCUSATE SODIUM, USP  
Stool Softener Laxative  
Softgel **100 mg**

**DOCUSATE SODIUM**

docusate sodium capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60687-129
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

**Product Characteristics**

<b>Color</b>	red (Reddish)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	SCU1
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:60687-129-01	100 in 1 BOX, UNIT-DOSE	11/25/2015	
1	NDC:60687-129-11	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	11/25/2015	

**Labeler** - American Health Packaging (929561009)

**Registrant** - Swiss Caps Romania (565466997)

### Establishment

Name	Address	ID/FEI	Business Operations
Swiss Caps Romania		565466997	manufacture(60687-129)

### Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(60687-129)