

## **STOOL SOFTENER EXTRA STRENGTH- docusate sodium capsule, liquid filled Hy-Vee**

*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 250 mg

#### **Purpose**

Stool softener laxative

#### **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 presently taking mineral oil, unless directed 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 right away.

#### **Directions**

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

#### **Other information**

- each softgel contains: **sodium 15 mg**
- store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)

**Inactive ingredients** □

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol\*, purified water, sorbitol special

\*may contain this ingredient

**Questions or comments?**

Call toll free **1-800-289-8343 Monday-Friday 9AM-4PM CST**

**Principal Display Panel**

Extra Strength Stool Softener

DOCUSATE SODIUM, 250 mg

Relieves Constipation

Softgels\*\*

\*\*Liquid-Filled Capsules

DISTRIBUTED BY HY-VEE, INC.

5820 WESTOWN PARKWAY

WEST DES MOINES, IA 50266

www.hy-vee.com

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

**Package Label**

**Hy-Vee**

**Extra Strength Stool Softener**  
DOCUSATE SODIUM, 250 mg

**Relieves Constipation**

**100 Softgels\*\***  
ACTUAL SIZE  
\*\* Liquid-Filled Capsules

NDC 42507-258-01

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

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Ask a doctor before use if you have ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks

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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.

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SATISFACTION GUARANTEED  
CALL 1-800-289-8343  
www.hy-vee.com

0 175450 112371 5

Lot No.:  
PLD-B210A  
LB001732

Exp. Date:

**Hy-Vee Extra Strength Stool Softener Softgel**

**STOOL SOFTENER EXTRA STRENGTH**

docusate sodium capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42507-258
<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	250 mg

**Inactive Ingredients**

<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 GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

**Product Characteristics**

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	P20;SCU1
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-258-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2014	

**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	04/30/2014	

**Labeler** - Hy-Vee (006925671)