

**STOOL SOFTENER LAXATIVE EXTRA STRENGTH- docusate sodium capsule, liquid filled**

**TOP CARE (Topco Associates LLC)**

*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 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 last 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 between 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, elatin, glycerin, mannitol, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol

**Questions or comments?**

Call toll free **1-888-423-0139**

**Principal Display Panel**

EXTRA STRENGTH

Stool Softener

DOCUSATE SODIUM, 250 mg

STOOL SOFTENER LAXATIVE

- Easy to swallow
- Relieves constipation

SOFTGELS

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELT GROVE VILLAGE, IL 60007

[www.topcarebrand.com](http://www.topcarebrand.com)

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**Product Label**

NDC:36800-568-10

**TopCare health™**

**EXTRA STRENGTH**

**Stool Softener**

DOCUSATE SODIUM, 250 mg  
STOOL SOFTENER LAXATIVE

- Easy to Swallow
- Relieves Constipation

**100 SOFTGELS** actual size

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

**Drug Facts**

**Active ingredient (in each softgel)** Docusate sodium 250 mg Stool softener laxative

**Uses** ■ 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

**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 (59-66°F)  
■ store between 20-25°C (68-77°F); excursions permitted between 15-30°C

**Inactive ingredients** edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol

**Questions or comments?**  
Call toll free 1-888-423-0139


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PLD-F510A  
L3007169

Lot No.:  
Exp. Date:

**QUALITY GUARANTEED**



36800 13587 1

**TOPCARE HEALTH Extra Strength Stool Softener**

**STOOL SOFTENER LAXATIVE EXTRA STRENGTH**

docusate sodium capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-568
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SORBITAN</b> (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
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-568-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/29/2019	

**Labeler** - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022

TOP CARE (Topco Associates LLC)