# 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.

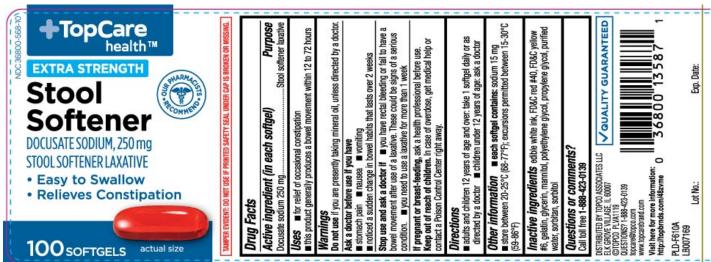
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#### **Product Label**



## TOPCARE HEALTH Extra Strength Stool Softener

#### STOOL SOFTENER LAXATIVE EXTRA STRENGTH

docusate sodium capsule, liquid filled

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-568

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) DOCUSATE SODIUM 250 mg

## **Inactive Ingredients**

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZ B9127XOA)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
GELATIN (UNII: 2G86QN327L)

GLYCERIN (UNII: PDC6A3C0OX)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KOOR)

SORBITOL (UNII: 506T60A25R)

MANNITOL (UNII: 30WL53L36A)

SORBITAN (UNII: 6092ICV9RU)

#### **Product Characteristics**

roduct characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	P20
Contains			

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)

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