

**DULCOLAX STOOL SOFTENER- docusate sodium capsule, liquid filled
Chattem, Inc.**

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.

Dulcolax Stool Softener - Patheon

Drug Facts

Active ingredient (in each capsule)

Docusate sodium (USP) 100 mg

Purpose

Stool softener laxative

Use

- for relief of occasional constipation and irregularity
- this product 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 or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. 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

take with a glass of water

adults and children 12 years of age and over 1 to 3 capsules daily. This dose
may be taken as a single daily dose or in divided doses.

children 2 to under 12 years of age 1 capsule daily

children under 2 years of age ask a doctor

Other information

- each capsule contains: **sodium 6 mg**
- store at 20°-25°C (68°-77°F). Protect from excessive humidity
- contains FD&C Yellow No. 6
- do not use this product if the safety seal under the cap is torn or missing

Inactive ingredients

FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol 400, propylene glycol, sorbitan, sorbitol, water

Questions?

Call **1-866-844-2798** or visit **www.Dulcolax.com**

Keep carton as it contains important product information.

PRINCIPAL DISPLAY PANEL

Dulcolax

Stool Softener

25 Liquid Gels



DULCOLAX STOOL SOFTENER

docosate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0221
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	Dulcolax
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0221-4	1 in 1 CARTON	08/01/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41167-0221-2	1 in 1 CARTON	08/01/2020	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41167-0221-3	1 in 1 CARTON	08/01/2020	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41167-0221-9	1 in 1 CARTON	08/01/2020	
4		30 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	08/01/2020	

Labeler - Chattem, Inc. (003336013)

Revised: 3/2021

Chattem, Inc.