

**SURFAK STOOL SOFTENER- docusate calcium capsule, gelatin coated
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.

Surfak Stool Softener Original Formula

Drug Facts

Active ingredient

(in each softgel)

Docusate calcium 240 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 12 to 72 hours

Warnings

Do not use

- when stomach pain, nausea or vomiting are present unless directed by a doctor

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts over 2 weeks

Ask a doctor or pharmacist before use

if you are presently taking mineral oil

Stop use and ask a doctor if

- you have rectal bleeding or failure to have a bowel movement after use. 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 or over: one softgel daily
- children under 12 years of age: ask a doctor

Other information

- protect from heat, humidity and light

Inactive ingredients

blue 1, corn oil, gelatin, glycerin, polyvinyl acetate phthalate, propylene glycol, red 40, sorbitol, titanium dioxide (245-198)

PRINCIPAL DISPLAY PANEL

Formerly Kaopectate® Stool Softener
 Surfak® Stool Softener original formula
 10 SoftGels 240 mg docusate calcium per softgel



SURFAK STOOL SOFTENER

docusate calcium capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-6100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE CALCIUM (UNII: 6K7YS503HC) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE CALCIUM	240 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
CORN OIL (UNII: 8470G57WFM)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	Surfak
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-6100-6	1 in 1 CARTON	01/01/2009	08/31/2012
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-6100-2	3 in 1 CARTON	01/01/2009	12/07/2017
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167-6100-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2009	12/07/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	01/01/2009	12/07/2017

Labeler - Chattem, Inc. (003336013)

Revised: 1/2009

Chattem, Inc.