STOOL SOFTENER- docusate sodium capsule, liquid filled Strategic Sourcing Services 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.

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- 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
- 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

• take only by mouth. Doses may be taken as a single daily dose or in divided doses.

| adults and children 12 years and over | take 1-3 softgels daily |
|---------------------------------------|-------------------------|
| children 2 to under 12 years of age | take 1 softgel daily |
| children under 2 years | ask a doctor |

Other information

- each softgel contains: sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

D&C red #33*, D&C yellow #10*, edible ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin*, medium-chain triglycerides*, polyethylene glycol, propylene glycol*, purified water, sorbitan, sorbitol, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE COLACE® ACTIVE INGREDIENT**

Stool Softener

Docusate Sodium, 100 mg

Relief of occasional Constipation

SOFTGELS

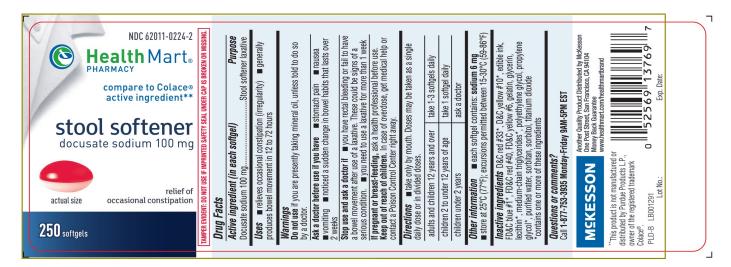
Another quality product distributed by McKesson

One post street, San Francisco, CA 94104

**This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®.

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

Product Label



Docusate sodium 100 mg softgels

STOOL SOFTENER

| locusate sodium cap | osule, liquid fil | led | | | | | |
|--|-------------------|----------------------------------|---------------|----------------------|-------------|-------------------|--|
| Product Informat | tion | | | | | | |
| Product Type | | HUMAN OTC DRUG | Item Co | n Code (Source) NDC | | C:62011-0224 | |
| Route of Administra | tion | ORAL | | | | | |
| | | | | | | | |
| Active Ingredient | | | | | | | |
| Ingredient Name DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | | | | | | Strength | |
| DOCUSATE SODIUM | (UNII: F05Q212 | JA0) (DOCUSATE - UNII:M/ | P27195AG) | DOCUSA | TE SODIUM | 100 mg | |
| Inactive Ingredie | nts | | | | | | |
| | | Ingredient Name | | | | Strength | |
| D&C RED NO.33 (UN | II: 9 DBA0 SBB0 | L) | | | | | |
| D&C YELLOW NO. 10 |) (UNII: 35SW5U | JSQ3G) | | | | | |
| FD&C BLUE NO.1 (U | NII: H3R47K3TB | D) | | | | | |
| FD&C RED NO.40 (U | NII: WZB9127X0 | DA) | | | | | |
| FD&C YELLOW NO. | 6 (UNII: H77VEI | 93A8) | | | | | |
| GELATIN (UNII: 2G86 | QN327L) | | | | | | |
| GLYCERIN (UNII: PDC | 6A3C0OX) | | | | | | |
| EGG PHO SPHO LIPID | | | | | | | |
| MEDIUM-CHAIN TRIG | | | | | | | |
| | | C IFIED (UNII: 3WJQ0SDW1A |) | | | | |
| PROPYLENE GLYCO | | (167V3) | | | | | |
| WATER (UNII: 059QF0 | | | | | | | |
| SORBITAN (UNII: 609 | , | | | | | | |
| SORBITOL (UNII: 506 | | | | | | | |
| TITANIUM DIO XIDE (| UNII: 15FIX9V2. | JP) | | | | | |
| Product Characte | ristics | | | | | | |
| Color | WHITE, RED | Score | | no sco | ore | | |
| Shape | OVAL | Size | | 12mm | | | |
| Flavor | | Imprint | Code | | 78;SCU2 | | |
| Contains | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | | Package Description | | - | | arketing End Date | |
| | | , ,1 | | 08/13/2013 12/30/202 | | | |
| 2 NDC:62011-0224-2 | 250 in 1 BOTTI | .E; Type 0: Not a Combinatio | n Product (|)8/13/2013 | 12/30/2023 | 1 | |
| Marketing Info | ormation | | | | | | |
| Marketing Categ | | ication Number or Monog | graph Citatio | on Marketing Start | Date Market | ting End Dat | |
| | | | | 0 | | | |

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - P & L Development, LLC (079765031)

Revised: 12/2019

Strategic Sourcing Services LLC