

STOOL SOFTNER- docusate sodium capsule, liquid filled
NuCare Pharmaceuticals, 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.

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener

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 stool softener 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 (1-800-222-1222).

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 |
| | take 1 softgel |

| | |
|-------------------------------------|----------------------|
| children 2 to under 12 years of age | take 1 softgel daily |
| children under 2 years | ask a doctor |

Other information

- **Tamper Evident: do not use if safety seal under cap is broken or missing**
- each capsule contains: **sodium 6 mg**
- **VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15 °-30 °C (59 °-86 °F).

Keep tightly closed.

This Package for Households Without Young Children

Inactive ingredients

D&C Red #33, Edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special, titanium dioxide

Questions?

Adverse drug event call: (800) 687-0176 Mon- Fri 8 AM to 4 PM

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

NuCare Pharmaceuticals, Inc.

NDC 68071-4218-6
Lot #: 000000 Exp. Date: 00-00

Docusate Sodium 100mg #60 Softgels

Each softgel contains:
Docusate Sodium 100mg.....Stool Softener
FD & C Yellow #6

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 stool softener laxative for more than 1 week. If pregnant or breast feeding, ask a health professional before use. In the case of overdose, get medical help or contact a Poison Control Center right away (1800-222-1222)

Oval Clear-Maroon/White Off-White Softgel Printed: "SCUZ"

Product #: P0083060
WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED TEMPERATURE 59-86°F.

STOOL SOFTNER

docusate sodium capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68071-4218(NDC:66424-399) |
| 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 |
|---|----------|
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| SORBITOL (UNII: 506T60A25R) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|--------------------------------------|--------------|----------|
| Color | red (Two toned- white and clear red) | Score | no score |
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | SCU2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68071-4218-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 01/09/2018 | |
| 2 | NDC:68071-4218-4 | 40 in 1 BOTTLE; Type 0: Not a Combination Product | 01/09/2018 | |
| 3 | NDC:68071-4218-6 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 01/09/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 03/01/2016 | |

Labeler - NuCare Pharmaceuticals, Inc. (010632300)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|---------------------|
| NuCare Pharmaceuticals, Inc. | | 010632300 | repack(68071-4218) |