## STOOL SOFTENER- docusate sodium capsule, liquid filled EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART 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.

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## **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, edible ink, FD&C blue #1\*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol\*, purified water, sorbitan, sorbitol, titanium dioxide

\*contains one or more of these ingredients

## Questions or comments?

1-888-287-1915

## **Principal Display Panel**

# Compare to Colace® Regular Strength Stool Softener Active Ingredient† Stool Softener

Docusate Sodium, 100mg

Stool Softener Laxative

- Gentle
- Dependable
- Stimulant-free

### **SOFTGELS**

†This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® Regular Strength Stool Softener.

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

**DISTRIBUTED BY: Wal-Mart Inc.,** 

Bentonville, AR 72716

#### **Product Label**



**EQUATE Stool Softener Laxative** 

## STOOL SOFTENER

docusate sodium capsule, liquid filled

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49035-078 |
| Route of Administration | ORAL           |                    |               |

| Active Ingredient/Active Moiety                                 |                          |          |  |
|---|--------------------------|----------|--|
| Ingredient Name   | <b>Basis of Strength</b> | 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 BLUE NO. 1 (UNII: H3R47K3TBD) |          |  |
| FD&C RED NO. 40 (UNII: WZB9127XOA) |          |  |

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

GELATIN (UNII: 2G86QN327L)

GLYCERIN (UNII: PDC6A3C0OX)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWIA)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KOOR)

SORBITAN (UNII: 6092ICV9RU)

SORBITOL (UNII: 506T60A25R)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

| Product Characteristics |            |              |             |
|-------------------------|------------|--------------|-------------|
| Color                   | red, white | Score        | no score    |
| Shape                   | OVAL       | Size         | 12mm        |
| Flavor                  |            | Imprint Code | P10;SCU2;D1 |
| Contains                |            |              |             |

| F | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:49035-<br>078-41 | 140 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2017              | 12/31/2024            |  |
| 2 | NDC:49035-<br>078-14 | 140 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2017              | 12/31/2024            |  |
| 3 | NDC:49035-<br>078-60 | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 12/31/2017              | 12/31/2024            |  |
| 4 | NDC:49035-<br>078-28 | 280 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2017              | 12/31/2024            |  |

| Marketing Information                                       |         |                         |                       |
|---|---------|-------------------------|-----------------------|
| Marketing Application Number or Monograph Category Citation |         | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph not final                                     | part334 | 12/31/2017              | 12/31/2024            |
|   |         |                         |                       |

Labeler - EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC) (051957769)

Revised: 2/2023 EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC)