DOCUSATE SODIUM- docusate sodium capsule, liquid filled
McKesson Corporation

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 capsule)*

Docusate Sodium 100mg

Purpose

Stool Softener

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation.
- This product generally produces a bowel movement within 12 to 72 hours.

Warnings

Do not use

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for longer than 1 week unless directed by a doctor

Ask a doctor before use if you notice a sudden change in bowel habits that persists over a period of 2 weeks.

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use

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 over 12 years of age:** take 1-2 capsules, preferably at bedtime
- **Children 6-12 years of age:** take 1 capsule at bedtime

Other information

- **each capsule contains:** sodium 5 mg
- store at controlled room temperature 15° - 30°C (59° - 86°F)

Inactive ingredients

FD&C red #40, gelatin, glycerin, polyethylene glycol, propyleneglycol and sorbitol special. May also contain: D&C yellow #10, FC&C yellow #6 and purified water.

HOW SUPPLIED

Product: 63739-478

Docusate Sodium

NDC 63739-478-02

SKY

DOCUSATE SODIUM STOOL SOFTENER

Softgels,100mg
UD 300 Softgels (30x10)

(01) 10363739478029

SKY

DOCUSATE SODIUM STOOL SOFTENER

NDC 63739-478-02

Softgels,100mg
UD 300 Softgels (30x10)

DOCUSATE SODIUM STOOL SOFTENER

NDC 63739-478-02

Drug Facts

Active ingredient (in each softgel) — ***Purpose***
Docusate sodium 100 mg — 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 (1-800-222-1222) right away. ▶

Drug Facts (continued)

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 to 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 5 mg
■ store at 25°C (77°F); excursions permitted between 15 and 30°C (59 and 86°F)

Inactive ingredients gelatin, polyethylene glycol, purified water, glycerol palm free, sorbitol, FD&C red #40, FD&C yellow #6.

This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace®.

Manufactured By: SwissCaps Romania
Str. Carol I, NR. 20, Cornu 107180, Romania

SKY Distributed By:
McKesson Corporation
Memphis, TN 38141

PKCP18565
Product of Romania

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63739-478(NDC:61301-8001)
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)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red (Reddish)	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739-478-01	25 in 1 BOX, UNIT-DOSE	11/09/2010	02/28/2016
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63739-478-10	10 in 1 BOX, UNIT-DOSE	11/09/2010	02/28/2016
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63739-478-48	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2017	09/21/2017
4	NDC:63739-478-40	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2017	09/21/2017
5	NDC:63739-478-02	30 in 1 BOX, UNIT-DOSE	07/01/2021	
5		10 in 1 BLISTER PACK; 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	11/09/2010	

Labeler - McKesson Corporation (140529962)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Packaging Resources Inc.		960203917	repack(63739-478)

Revised: 8/2021

McKesson Corporation