DOCUSATE SODIUM- docusate sodium capsule, liquid filled
McKesson Corporation

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
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)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

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 Drug	505G(a)(3)	11/09/2010	

Labeler - McKesson Corporation (140529962)

Registrant - McKesson Corporation dba SKY Packaging (140529962)

Establishment

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

Revised: 1/2024 McKesson Corporation