

DOCUSATE SODIUM- docusate sodium capsule, liquid filled
Asclemed USA, Inc.

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

Ask a doctor before use if you

- have stomach pain, nausea or vomiting
- have a sudden change in bowel habits that persists over a period of 2 weeks
- are presently taking mineral oil

Stop use and ask a doctor if

- you need to use a laxative longer than 1 week
- you have rectal bleeding or fail to have a bowel movement. These could be signs of a serious condition.

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

- do not exceed recommended dose
- adults and children 12 years and older: take 1-3 softgels daily until first bowel movement; 1 softgel daily thereafter, or as directed by a doctor
- children under 12: consult a doctor

Other information

- **each softgel contains:** sodium 7 mg. Very low sodium
- store at 59°-77°F (15°-25°C)
- keep tightly closed
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.


Inactive ingredients

FD&C red #40, FD&C yellow #6 (sunset yellow), gelatin, glycerin, PEG, sorbitol special, water.

Repackaged/Relabeled by:
 Enovachem PHARMACEUTICALS
 Torrance, CA 90501


Package Label

Relabeled By:




379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Docosate Sodium 100mg
 NDC: 76420-225-30
 Qty: 30



Distributed By: Geri-Care Pharmaceuticals Corp.
 Source NDC: 57896-401-03
 Description: red/oval/SCU1
 Lot #: 00000000 Exp: 00/00/0000
 Batch #: 00000000
 Drug Status: OTC



(01) 0 0376420 22530 0
 (17) 220706
 (10) 00000000
 (21) 151005


CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

Docosate Sodium 100mg
 NDC: 76420-225-30
 S/N:151005
 Qty: 30

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 NDC: 76420-225-30
 S/N:151005
 Qty: 30

Packaged By:




379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Docosate Sodium 100mg
 NDC: 76420-225-30
 Qty: 30



Distributed By: Geri-Care Pharmaceuticals Corp.
 Source NDC: 57896-401-XX
 Description: red/oval/SCU1
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: OTC



(01) 0 0376420 22530 0
 (17)
 (10) 00000000
 (21)

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 NDC: 76420-225-30
 S/N:
 Qty: 30

Packaged By:



Docosate Sodium 100mg
 NDC: 76420-225-60

Enovachem PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1408
 Torrance, CA 90501

Docosate Sodium 100mg
 NDC: 76420-225-60

Qty: 60

Distributed By: Geri-Care Pharmaceuticals Corp.
 Source NDC: 57896-401-XX
 Description: red/oval/SCU1
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: OTC



(01) 0 0376420 22560 7
 (17)
 (10) 00000000
 (21)

S/N:
 Qty: 60

Docosate Sodium 100mg
 NDC: 76420-225-60
 S/N:
 Qty: 60

Docosate Sodium 100mg
 NDC: 76420-225-60
 S/N:
 Qty: 60

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Packaged By:

Enovachem PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1408
 Torrance, CA 90501

Docosate Sodium 100mg
 NDC: 76420-225-90

Qty: 90

Distributed By: Geri-Care Pharmaceuticals Corp.
 Source NDC: 57896-401-XX
 Description: red/oval/SCU1
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: OTC



(01) 0 0376420 22590 4
 (17)
 (10) 00000000
 (21)

Docosate Sodium 100mg
 NDC: 76420-225-90
 S/N:
 Qty: 90

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 NDC: 76420-225-90
 S/N:
 Qty: 90

Docosate Sodium 100mg
 NDC: 76420-225-90
 S/N:
 Qty: 90

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

DOCUSATE SODIUM

docosate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-225(NDC:57896-401)
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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
SORBITOL (UNII: 506T60A25R)	

WATER (UNII: 059QF0KO0R)

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

MANNITOL (UNII: 3OWL53L36A)

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:76420-225-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2022	
2	NDC:76420-225-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2022	
3	NDC:76420-225-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/01/2000	

Labeler - Asclemed USA, Inc. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	repack(76420-225) , relabel(76420-225)

Revised: 10/2023

Asclemed USA, Inc.