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.

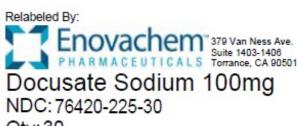
Inactive ingredients

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



Qty: 30

Distributed By

Distributed By: Geri-Care Pharmaceuticals Corp.

Source NDC: 57896-401-03 Description: red/oval/SCU1

Lot #: 00000000 Batch #: 00000000 Drug Status: OTC Exp: 00/00/0000

(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]. Docusate Sodium 100mg NDC: 76420-225-30 S/N:151005 Qty: 30

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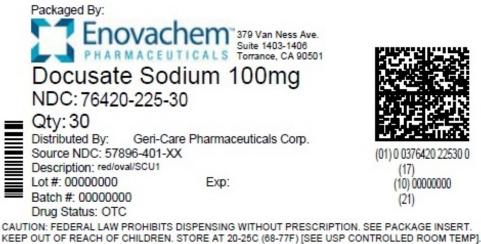
> S/N: Qty: 30

Docusate Sodium 100mg NDC: 76420-225-30

S/N: Qty: 30

Docusate Sodium 100mg NDC: 76420-225-30

S/N: Qty: 30





Docusate 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 #: 000000000

Drug Status: OTC 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].



(17)(10) 00000000

(21)

(01) 0 0376420 22590 4

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Docusate Sodium 100mg

NDC: 76420-225-60

Docusate Sodium 100mg NDC: 76420-225-60

Docusate Sodium 100mg NDC: 76420-225-90

S/N: Qty: 90

S/N:

S/N

S/N:

Qty: 60

Qty: 60

Qty: 60

Docusate Sodium 100mg NDC: 76420-225-90

S/N: Qty: 90

Docusate Sodium 100mg

NDC: 76420-225-90

S/N: Qty: 90



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

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

docusate sodium capsule, liquid filled

Product Information

HUMAN OTC DRUG Product Type 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: B697894SGQ)

SORBITOL (UNII: 506T60A25R)

WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MANNITOL (UNII: 30WL53L36A)	

Product Characteristics			
Color	red (reddish)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	SCU1
Contains			

P	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.