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

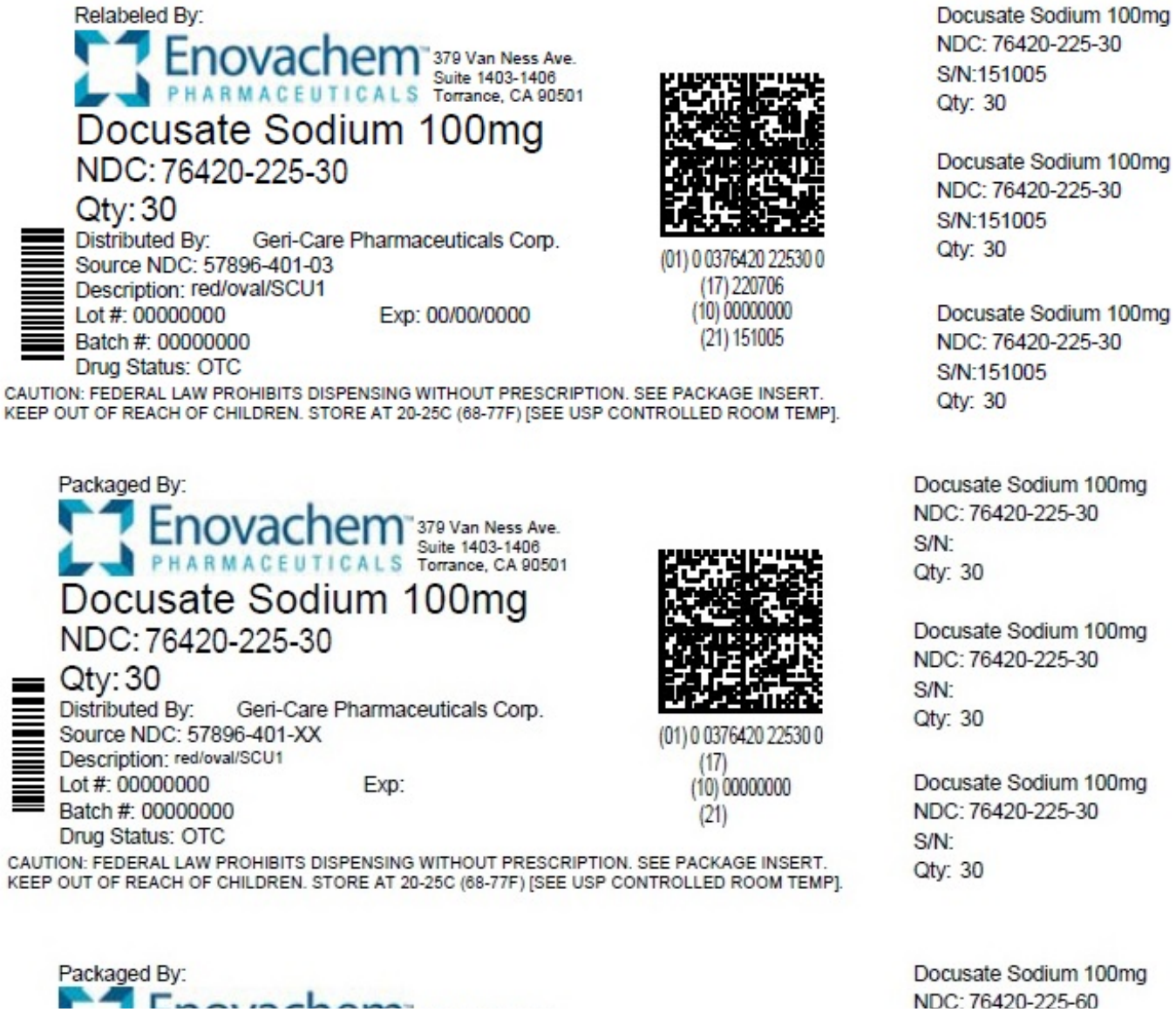
• **each softgel contains:** sodium 7 mg. Very low sodium
• store at 59°-77°F (15°-25°C)
• keep tightly closed
• **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

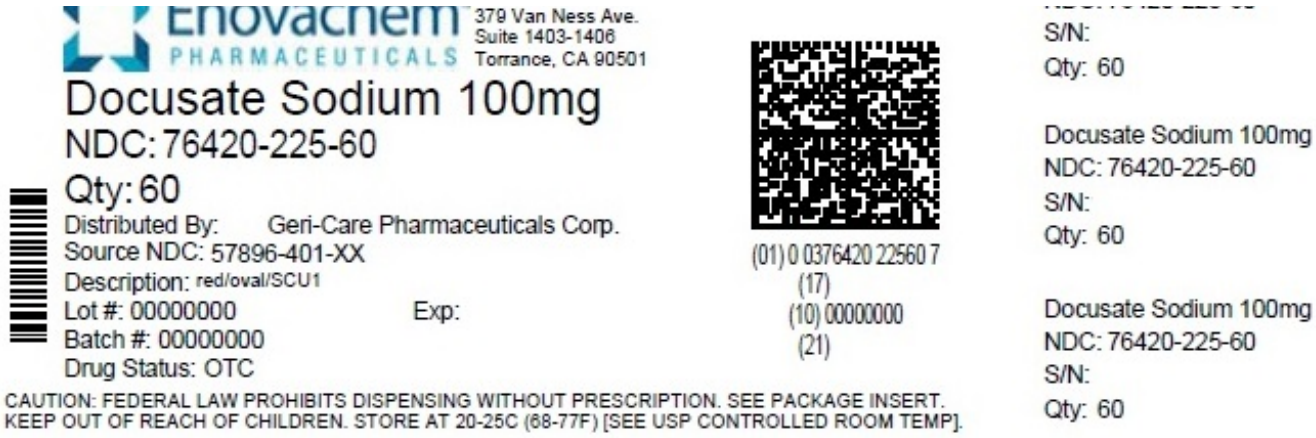
Inactive ingredients

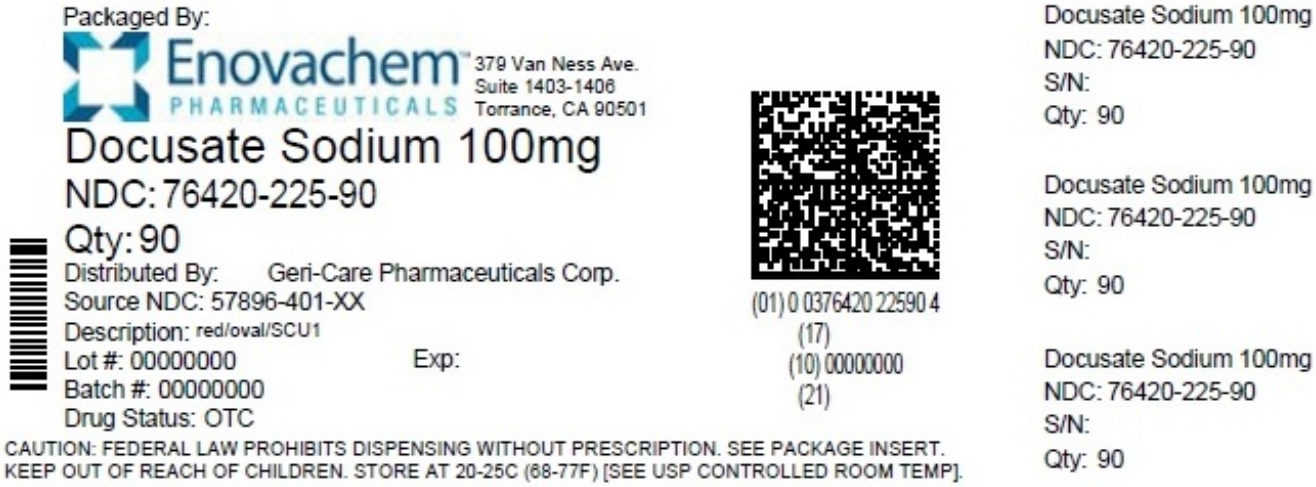
FD&C red #40, FD&C yellow #6 (sunset yellow), gelatin, glycerin, PEG, sorbitol special, water.

Repackaged/Relabeled by:
Enovachem PHARMACEUTICALS
Torrance, CA 90501

Package Label







DOCUSATE SODIUM

docusate 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: B697894SGQ)	
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.