

DOCUSATE SODIUM- docusate sodium capsule, liquid filled
Precision Dose, Inc.

Docusate Sodium capsule

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 250 mg

Purpose

Stool Softener

Uses

- For the relief of occasional constipation.
- Helps to prevent dry, hard stools.
- 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 one week unless directed by a doctor.

Ask a doctor before use if you noticed a sudden change in bowel habits that persists over a period of two 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

Adult and Children over 12 years of	Take orally 1 softgel preferably at bedtime for 2- 3 days or until bowel movements are normal, or
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age	as directed by a doctor.
Children under 12 years of age	Do not use this product for children under 12 years of age, unless directed by a doctor.

Other information

- **Each softgel contains 13 mg of Sodium.**
- **Store at room temperature between 15°C to 25°C (59°F to 77°F).**

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, Gelatin, Glycerin, Ink (Edible), Polyethylene Glycol, Propylene Glycol, Purified Water, Sorbitol.

How Supplied

NDC 68094-052-61

Unit Dose Packages of 100 Softgels (10×10) per Carton

Distributed by:

National Vitamin Company

Casa Grande, AZ 85122

Packaged by:

Precision Dose, Inc.

South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228 or email druginfo@precisiondose.com

LI1459 Rev. 06/21

PRINCIPAL DISPLAY PANEL - 250 mg Softgel Blister Pack Carton

Precision Dose™

NDC 68094-052-61

Unit Dose

Docosate Sodium, USP

250 mg Softgels

100 Softgels

(10 x 10)

(in each softgel)

Docosate Sodium 250 mg Stool Softener

Each softgel contains 13 mg of Sodium.

USUAL DOSE: SEE ENCLOSED INSERT.

Store at room temperature between
15°C to 25°C (59°F to 77°F).

Keep out of reach of children.

Hospital Use Only.

LC1458

R0

Packaged by:
Precision Dose, Inc.
South Beloit, IL 61080



NDC 68094-052-61

Unit Dose

Docosate Sodium, USP
250 mg Softgels

100 Softgels
(10 x 10)

(in each softgel)

Docosate Sodium 250 mg...Stool Softener

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USUAL DOSE: SEE ENCLOSED INSERT.

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LC1458

R0

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Docosate Sodium, USP
250 mg Softgel
For Hospital Use Only

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LI1459 Rev. 06/21

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-052(NDC:54629-601)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	NV12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-052-61	10 in 1 CARTON	09/30/2022	10/31/2024
1	NDC:68094-052-59	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	M007	09/30/2022	10/31/2024

Labeler - Precision Dose, Inc. (035886746)

Establishment

Name	Address	ID/FEI	Business Operations
Precision Dose, Inc.		035886746	REPACK(68094-052)

Revised: 1/2024

Precision Dose, Inc.