DOCUSATE SODIUM- docusate sodium capsule, liquid filled Cardinal Health 107, LLC

Docusate Sodium, USP

Stool Softener

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 notice 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 you are pregnant or breast-feeding,

ask a healthcare professional before use.

Keep Out of Reach of Children.

In case of overdose, get medical help or contact a Poison Control Center right away.

This Unit Dose Package

is not child resistant and is Intended for Institutional Use Only.

If dispensed for outpatient use, a child-resistant container should be utilized

Directions

Adults and Children over 12	Take orally 1 softgel preferably at bedtime for
years of age	2-3 days or until bowel movements are normal, or 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).
- For identification purposes, each softgel will have an imprint that reads NV12.
- Bend at perforation before tearing

Inactive ingredients

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

Questions

Call 1-855-361-3993

Manufactured for:

AVKARE

Pulaski, TN 38478

AVPAK™

A PRODUCT OF AVKARE

Made in USA

Mfg. Formula 8064

Distributed by:

Cardinal Health

Dublin, OH 43017

L5365630-10724

L5365630-20724

Principal Display Panel

DOCUSATE SODIUM, USP 250 mg STOOL SOFTENER 10 SOFTGELS

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DOCUSATE SODIUM, USP 250 mg STOOL SOFTENER

10 SOFTGELS

Dietary Supplement

- Each softgel contains 13 mg of Sodium
- For identification purposes, each softgel will have an imprint that reads NV12.

Drug Facts

Active Ingredient (in each softgel) Purpose Docusate Sodium 250 mg Stool Softener

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

- For the relief of occasional constipation.
- Helps to prevent dry, hard stools.
 This product generally produces a bowel movement within 12 to 72 hours.

STORAGE: Store at Room Temperature between 15° C to 25° C (59° to 77° F).

WARNING: This Unit Dose package is not child resistant

and is Intended for Institutional Use Only.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

If pregnant or breast-feeding, ask a healthcare professional before use. In case of overdose, get medical help or contact a Poison Control Center right away.

If dispensed for outpatient use, a child-resistant container should be utilized.

Bend at perforation before tearing

Questions? Call 1-855-361-3993

Manufactured for: AvKARE Pulaski, TN 38478 AVPAK™ A PRODUCT OF AVKARE Made in USA Mfg. Formula 8064

Distributed by Cardinal Health Dublin, OH 43017

L5365630-10724

Lot: Exp: Distributed by Cardinal Health

Dublin, OH 43017

L5365630-20724

Drug Facts (continued)

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 notice 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.

Directions

Adults and children over 12 years of age	Take orally 1 softgel preferably at bedtime for 2-3 days or until bowel movements are normal, or 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.

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-4341(NDC:50268-268)
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: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	NV12	
Contains				

I	Packaging					
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:55154- 4341-0	10 in 1 BAG	05/17/2017			
1	L	1 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	05/17/2017		

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 7/2024 Cardinal Health 107, LLC