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

Keep Out of Reach of Children.

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

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 or you fail to have a bowel movement after use.

If you are pregnant or breast-feeding,

ask a healthcare professional before use.

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 30°C (59°F to 86°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

Generic Section

Manufactured for

AVKARE

Pulaski, TN 38478

AVPAK™

A PRODUCT OF AVKARE

Made in USA

Mfg. Formula 8064

Distributed by:

Cardinal Health

Dublin, OH 43017

L5365630-10721

Principal Display Panel

Docusate Sodium, USP

250 mg

10 Softgels



Z117

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		

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 inactive ingredients.

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

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

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

If dispensed for outpatient use, a of Manufactured for AvKARE Pulaski, TN 38478 AVPAK™ A PRODUCT OF AvKARE Questions? Call 1-855-361-3993 Bend at perforation before tearing Made in USA Mfg Formula 8064 Distributed by Cardinal Health Dublin, OH 43017

L5365630-10721

LOT #: XXXXXXXXXX EXP. DATE: XX/XX/XX

Distributed by Cardinal Health Zanesville, OH 43701 L5365630-20721

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 fall 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 bowe 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				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:55154- 4341-0	10 in 1 BAG	05/17/2017				
1		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: 11/2023 Cardinal Health 107, LLC