# DOCUSATE SODIUM- docusate sodium capsule, liquid filled AvPAK

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**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	Take orally 1 softgel preferably	
Children over 12	at bedtime for	
years of age	2-3 days or until bowel	
	movements are normal, or as	
	directed by a doctor.	
Children under 12	Do not use this product for	
years of age	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).
- Do not use if printed seal under cap is broken or missing.
- For identification purposes, each softgel will have an imprint that reads NV12.

### **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

# Package/Label Principal Display Panel

NDC 50268-268-15 AvKARE Docusate Sodium, USP Stool Softener 250 mg Each 100 Softgels

USA AV Rev. 05/16 (P)

Manufactured for: AvKARE, Inc. Pulaski, TN 38478 NDC 50268-268-15

# **DOCUSATE** SODIUM, USP

STOOL SOFTENER

250 mg

50 Softgels (5 X 10) Unit Dose



NDC 50268-268-15

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**Dietary Supplement** 

# **Drug Facts**

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

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

USA Mfg. Formula 8064

AV Rev. 05/16 (P)





# 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.

If pregnant or breast-feeding, ask a healthcare professional before use.

Keep out of the reach of children.

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

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.

# Drug Facts (continued)

### Other Information

- Each softgel contains 13 mg of Sodium.
- Store at room temperature between 15°C to 25°C (59° to 77°F).
- For identification purposes, each softgel will have an imprint that reads NV12.

# **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, Inc. Pulaski, TN 38478

Mfg. Formula 8064

AV Rev. 05/16 (P)

# **DOCUSATE SODIUM**

docusate sodium capsule, liquid filled

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50268-268(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 (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			

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:50268-268- 15	50 in 1 BOX	05/17/2017		
	1	NDC:50268-268- 11	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 -** AVPAK (832926666)

Revised: 10/2023 AvPAK