DOCUSATE SODIUM- docusate sodium capsule, liquid filled
AvPAK

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 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.

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

5026826815

NDC 50268-268-15

DOCUSATE SODIUM, USP

STOOL SOFTENER

250 mg

50 Softgels (5 X 10) Unit Dose

5026826815

Dietary Supplement

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.

USA

Mfg. Formula 8064

AV Rev. 05/16 (P)

AVPAK

A PRODUCT OF AvKARE

Peel Here

Drug Facts (continued)

WARNINGS Do not use:

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- 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 15ºC to 25ºC (59º to 77ºF).
- 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			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50268-268-15	50 in 1 BOX, UNIT-DOSE	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 not final	part334	05/17/2017	

Labeler - AvPAK (832926666)