

DOCUSATE SODIUM- docusate sodium capsule, liquid filled
APNAR PHARMA LP

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 SOFTGELS

Active Ingredient (In each softgel)

Docusate Sodium.... 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless told to do so by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be a signs of a serious condition.
- you need to use a stool softner laxative for more than 1 week

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 (1-800-222-1222) right away.

Directions

take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over : take 1 to 3 softgels daily

children 2 to under 12 years of age : take 1 softgel daily

children under 2 years : ask a doctor

Other Information

each softgel contains: sodium 5 mg
store between 20°C - 25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)

Gelatin, Glycerin, Sorbitol Sorbitan solution, Purified water, D&C Red #40, D&C Yellow #6, White Ink

Questions or Comments ?

Call 1-855-642-2594

Compare to the active ingredient in Colace® Regular Strength Stool Softener†

†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

Rev.: 03/2023

Manufactured by:
Apnar Pharma LLP
East Windsor, NJ 08520

NDC 24689-130-01

Docosate Sodium 100mg

Stool Softener Laxative

MADE IN USA

100 Softgels

NDC 24689-130-01

Compare to the active ingredient in Colace® Regular Strength Stool Softener



Docosate Sodium

100 MG

Stool Softener Laxative 100 Softgels



Manufactured by:
Apnar Pharma LLP
East Windsor, NJ 08520

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

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Inactive Ingredients Gelatin, Glycerin, Sorbitol, Sorbitan Solution, Purified water, D&C Red # 40, D&C yellow # 6, white ink.

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Rev.: 03/2023



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Lot #:

Exp date:

DOCUSATE SODIUM

docosate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24689-130
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C00X)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL (Oblong)	Size	13mm
Flavor		Imprint Code	AD2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24689-130-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M007	09/25/2023	

Labeler - APNAR PHARMA LP (079568229)

Establishment

Name	Address	ID/FEI	Business Operations
APNAR PHARMA LLP		118530917	analysis(24689-130) , manufacture(24689-130) , pack(24689-130)

Revised: 9/2023

APNAR PHARMA LP