

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

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: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

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 Drug	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: 1/2025

APNAR PHARMA LP