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

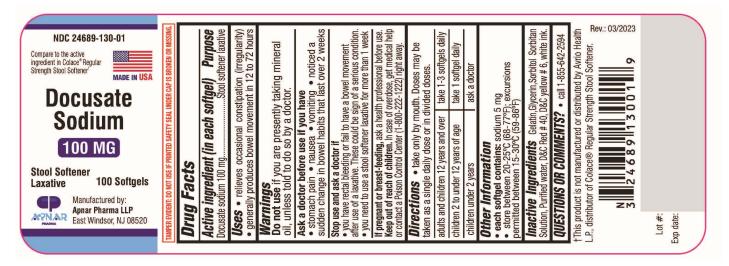
NDC 24689-130-01

Docusate Sodium 100mg

Stool Softener Laxative

MADE IN USA

100 Softgels



DOCUSATE SODIUM docusate 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 S	trength	Strength	
DOCUSATE SODIU	DIUM	100 mg				
Inactive Ingre	dients					
		Strength				
GELATIN (UNII: 2G8						
GLYCERIN (UNII: PD	C6A3C0OX)					
SORBITOL (UNII: 50)6T60A25R)					
SORBITAN (UNII: 60	092ICV9RU)					
WATER (UNII: 059Q	F0KO0R)					
FD&C RED NO. 40	(UNII: WZ B9127XOA)					
FD&C YELLOW NO	6 (UNII: H77VEI93A8)					
Product Chara	octeristics					
Color	red	Score		no score		
Shape	OVAL (Oblong)	Size	Size		13mm	
Flavor	Imprint Code		Code	AD2		
Contains						
Packaging						
# Item Code	Package Des	cription	Marketing Start Date		ting End ate	
1 NDC:24689-130- 01	100 in 1 BOTTLE; Type 0: N Product	ot a Combination 09	09/25/2023			
Marketing	Information					
	Application Number	er or Monograph			eting End	
Marketing Category	Citat		Date		Date	

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