DOCUSATE SODIUM- docusate sodium capsule, liquid filled Proficient Rx LP

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener

Uses

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

Warnings

Do not use

if you are currently taking mineral oil, unless directed by a doctor

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- have noticed a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use
- you need to use a stool softener 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 right away.

Directions

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 children under 2 years

take 1 softgel daily ask a doctor

Other information

- each capsule contains sodium 6 mg
- store at room temperature 15°-30°C (59°-86°F)
- Tamper Evident: Do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients: D&C red #33, Edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special

Questions?

Adverse drug event call (800) 687-0176

Principal Display Panel

Relabeled By:

Proficient Rx IP

Thousand Oaks, CA 91320





NDC 63187-476-00

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

#10

Docusate Sodium 100mg

#100 Softgel Capsules

Each softgel contains: Docusate Sodium 100mg Stool softener

Oval shaped, red (Two toned-white and clear red), unscored softgel imprinted with "51A"

Product ID: RD047600

Dist. By: SDA Laboratories, Inc., Greenwich, CT 06830 Store at room temperature 15°-30°C (59° -86° F)

Keep medication out of the reach of children

Docusate Sodium 100mg #100 Softgel Capsules Lot #:00000 SN# MASTER NDC 63187-476-00 Exp:00/00/00

Docusate Sodium 100mg #100 Softgel Capsules Lot #:00000 SN# MASTER NDC 63187-476-00 Exp:00/00/00

Docusate Sodium 100mg #100 Softgel Capsules Lot #:00000 SN# MASTER NDC 63187-476-00 Exp:00/00/00



GTIN: 00363187476007 SN# MASTER Exp. 00/00/00 Lot #:00000

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63187-476(NDC:66424-030)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	Docusate Sodium (UNII: F0502T2IA0) (Docusate - UNII:M7P27195AG)	Docusate Sodium	100 mg

Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics				
Color	red (Two toned- white and clear red)	Score	no score	
Shape	OVAL	Size	5mm	
Flavor		Imprint Code	51A	
Contains				

l	Packaging				
	# Item (Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:6318	37-476-	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	
	2 NDC:6318	87-476-	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	
	3 NDC:6318	87-476-	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	
	4 NDC:6318	37-476-	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	09/15/2010	

Labeler - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-476), RELABEL(63187-476)

Revised: 2/2024 Proficient Rx LP