

**STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
Preferred Pharmaceuticals Inc.**

DRUG FACTS

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

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

Stop use and ask a doctor if

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

If pregnant or breast-feeding,

ask a health care 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 1-3 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 7 mg
- store at 25°C (77°F); excursion permitted between 15-30°C (59-86°F)

Inactive ingredients

citric acid, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water sorbitol special, white edible ink

NDC 68788-8501-3

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

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

DOCUSATE SODIUM, 100 mg

STOOL SOFTENER LAXATIVE

Gentle, Dependable

Stimulant-free

SOFTGELS

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

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

DISTRIBUTED BY:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.majorpharmaceuticals.com

Repackaged By: Preferred Pharmaceuticals Inc.

Product Label


Docosate Sodium 100mg

Generic for Colace


Active ingredient (in each softgel): Docosate Sodium 100mg.....Stool Softener

Pkg Size: Exp Date:
Lot#:
Batch#:
Ins:
Mfg: Major Pharmaceuticals
Prod#:

Warning
Ask a doctor before use if you: have stomach pain, nausea, or vomiting, have a sudden change in bowel habits that persists over 2 weeks, are presently taking mineral oil. Stop use and ask a doctor if: you need to use a laxative longer than 1 week, you fail to have a bowel movement within 3 days, you have rectal bleeding. These could be signs of a serious condition. If pregnant or breast feeding ask a health professional before use. Keep out of reach of children. Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F). Softgel is oval, red, imprinted with PC1



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed

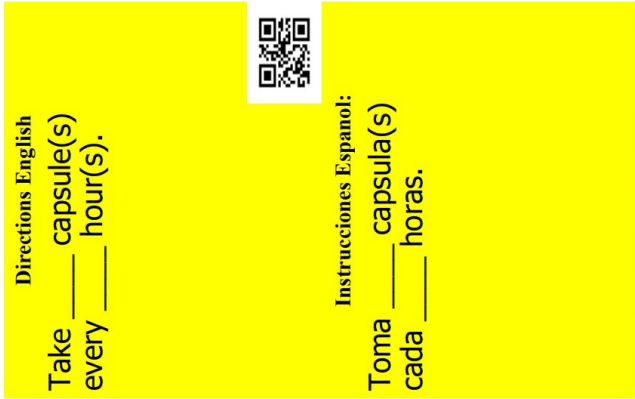


Docosate Sodium 100mg
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):

Docosate Sodium 100mg
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):

Docosate Sodium 100mg
Qty:
Insurance NDC:
Lot#: Bat#:

Docosate Sodium 100mg
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):



MAJOR Stool Softener Laxative

Log

Chart

Billing

Patient

Repackaged By: Preferred Pharmaceuticals Inc.

STOOL SOFTENER LAXATIVE			
docosate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8501(NDC:0904-7280)
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		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
GLYCERIN (UNII: PDC6A3C0OX)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
SORBITAN (UNII: 6O92ICV9RU)			

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE (Oval)	Size	13mm
Flavor		Imprint Code	PC1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8501-3	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/09/2023	
2	NDC:68788-8501-6	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/09/2023	
3	NDC:68788-8501-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	334	08/09/2023	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8501)

Revised: 4/2024

Preferred Pharmaceuticals Inc.