

STIMULANT LAXATIVE PLUS STOOL SOFTENER- docusate sodium 50 mg and sennosides 8.6 mg tablet, film coated

Preferred Pharmaceuticals, Inc.

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.

Drug Facts

Active Ingredients (in each tablet)

Docusate Sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool softener

Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 6 to 12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless told to do so by a doctor
- 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 continues over 2 weeks

Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after the use of a laxative.

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.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses

adults and children 12 years and over take 2-4 tablets daily
children 6 to under 12 years of age take 1-2 tablets daily
children 2 to under 6 years of age take upto 1 tablet daily
children under 2 ask a doctor

Other information

- each tablet contains: **calcium 10 mg, sodium 5 mg, Very Low Sodium**
- store at 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

croscarmellose sodium, dicalcium phosphate, FD&C Red #40, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium benzoate, talc, titanium dioxide

Questions or comments?

1-800-645-2158

RUGBY®

Repackaged by Preferred Pharmaceuticals, Inc.

NDC 68788-7674

Bottle of 60 NDC 68788-7674-06

Bottle of 100 NDC 68788-7674-01

Compare to the

active ingredients

in Colace® 2-IN-1*

Stimulant

Laxative

Plus Stool Softener

Docosate Sodium, 50 mg

Sennosides, 8.6 mg

50 mg/8.6 mg

Stimulant Laxative Plus Stool Softener

Generic for: Senokot-S®
 Each tablet contains: Docusate sodium 50mg...
 Stool Softener / Sennosides 8.6mg...Stimulant
 Laxative / calcium 10mg, sodium 5mg

Pkg Size: Exp Date:

Lot#: _____
 Batch#: _____
 Ins: _____
 Mfg: Rugby Laboratories; Livonia, MI
 Prod#: _____

Warning
 Do not use if you are taking mineral oil, for longer than one week, or when abdominal pain, nausea or vomiting is present. Ask a doctor if you have a sudden change of bowel habits that lasts over two weeks. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F). Tablet is round, red, imprinted with PH2.



Directions English
 Take ___ tablet(s)
 every ___ hours.



Instrucciones Espanol:
 Toma ___ tableta(s)
 cada ___ horas.

Stimulant Laxative Plus Stool Softener
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):
 Stimulant Laxative Plus Stool Softener
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):
 Stimulant Laxative Plus Stool Softener
 Qty: Ins:
 Insurance NDC:
 Lot#: Bat#:
 Stimulant Laxative Plus Stool Softener
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):

Log
 Chart
 Billing
 Patient

STIMULANT LAXATIVE PLUS STOOL SOFTENER

docusate sodium 50 mg and sennosides 8.6 mg tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7674(NDC:0536-1248)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0IIX) (SENNOSIDES - UNII:3FYP5M0IIX)	SENNOSIDES	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND (ROUND TABLET)	Size	10 mm
Flavor		Imprint Code	PH32
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7674-6	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2020	
2	NDC:68788-7674-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/28/2020	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)**Registrant** - Preferred Pharmaceuticals, Inc. (791119022)**Establishment**

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	REPACK(68788-7674)

Revised: 2/2020

Preferred Pharmaceuticals, Inc.