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 sings 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 take 2-4 tablets
children 12 years daily
and over
children 6 take 1-2 tablets
to under 12 daily
years of age
children 2 take upto 1 tablet
to under 6 years daily
of age
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 68788-7674-6

Compare to the

active ingredients

in Colace® 2-IN-1* Stimulant

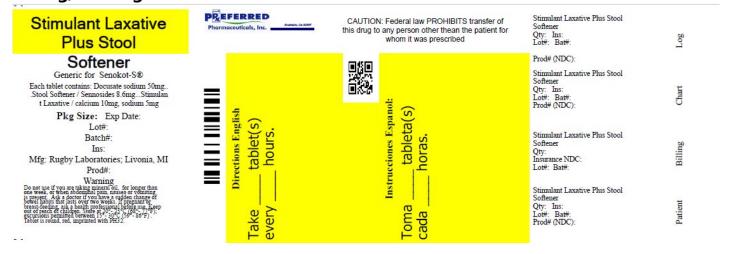
Laxative

Plus Stool Softener

Docusate Sodium, 50 mg

Sennosides, 8.6 mg

50 mg/ 8.6 mg



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: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg	

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
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	10mm
Flavor		Imprint Code	PH32
Contains			

P	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: 9/2023 Preferred Pharmaceuticals, Inc.