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

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 children 12 years	take 2-4 tablets
and over	daily
children 6 to under 12 years	take 1-2 tablets
of age	daily
children 2 to under 6 years of	take upto 1 tablet
age	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[®]

NDC 0536-1248-10

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

1000 TABLETS

Rugby NDC 0536-1248-10 Compare to the active ingredients in Colace [®] 2-IN-1* Stimulant Laxative	THOUT YOUNG CHILDREN	ssing	Purpose Stool softener Stimulant laxative	∎ ĝe	1 week unless tol nineral oil, unless pain _ nausea	e. 	away (1-800-222-1222). en as a single dally dose, loses	take 2-4 tablets daily take 1-2 tablets daily take up to 1 tablet daily	ask a doctor	sodium 5 mg, Very Low excursions permitted between	sodium, dicalcium stearate, microcrystalline alcohol, sodium benzoate,		by Avrio Health L.P., owner of the	R-titi Re-order No. 370792	5361 24810 9
Plus Stool Softener	LIM QTOH	USE IF SA En or mis	h tablet)	cion (irreguind	<pre>products for longer than f you are presently taking use if you have</pre>	a laxa conc conc	ay be tak	years and over years of age ears of age		10 mg, 77°F);	armellose ignesium polyvinyl		distributed by	Rev. 10/19	0
Docusate Sodium, 50 mg Sennosides, 8.6 mg	OR HOUSEHOLD	I: DO NOT Broki	ents (in each 50 mg	occasional constipation (irregularity) ovement in 6 to 12 hours	ve products if you are p i use if you	ask a doctor If you and after the use of a signs of a serious breast-feeding, as	Doses	12 6 y		on lins: calcium 20-25°C (68-	s crosc #40, mi glycol,	comments?	manufactured or k Colace [®] 2-IN-1.	: DRATORIES Park Drive 152 oratories.com	
50 mg/8.6 mg	ACKAGE F	TAMPER EVIDENT:	cacts ingredia sodium des 8.6 m	s occasion movement	tuse = laxative by a doctor = If so by a doctor doctor	and and and a stand	Pois the	id child 6 to un 2 to un	under 2	nformati ablet conta ■ store at (59-86°F)	ingred FD&C olyethy m diox	155	uct is not mai rademark Col	ed by: LABORATORII aurel Park Driv Al 48152 bylaboratories.c	
1000 Tablets	THIS P	TAMPE	Drug F Active Docusate Sennosid	Uses Telieves a bowel m	Warnin Do not u do so by to do so Ask a do	2 weeks Stop use an bowel move These could If pregnant	2000	adults ar children children	children	Other in each ta Sodium 15-30°C	Inactive phosphate, cellulose, p talc, titanlu	Questions 1-800-645-2	*This produ registered tr	Distribute RUGBY® 17177 N L Suite 233 Livonia, N www.rugh	

Product Inform	nation								
Product Type	roduct TypeHUMAN OTC DRUGItem Code (Source)NDC:0536-1248								
oute of Administration ORAL									
Active Ingredie	nt/Active	Moiety							
	Ingre	edient Name		Basis of S	trength	Strength			
SENNOSIDES (UNII:	3FYP5M0IJX) (S	ENNOSIDES - UNII:3FYP5M	10IJX)	SENNOSIDES		8.6 mg			
DOCUSATE SODIUM	(UNII: F05Q2	T2JA0) (DOCUSATE - UNII:N	17P27195AG)	DOCUSATE SC	DIUM	50 mg			
Inactive Ingred	lients								
		Ingredient Name	•		5	Strength			
CROSCARMELLOSE	SODIUM (UN	II: M28OL1HH48)							
CALCIUM PHOSPHA	TE, DIBASIC,	DIHYDRATE (UNII: 07TS)	Z97GEP)						
FD&C RED NO. 40 (UNII: WZ B912	7XOA)							
MAGNESIUM STEAR	ATE (UNII: 70	097M6I30)							
CELLULOSE, MICRO	CRYSTALLIN	E (UNII: OP1R32D61U)							
POLYETHYLENE GL	YCOL, UNSPE	CIFIED (UNII: 3W)Q0SDW	LA)						
POLYVINYL ALCOHO	DL, UNSPECI	FIED (UNII: 532B59J990)							
SODIUM BENZOATE	-	E5EU)							
TALC (UNII: 7SEV7J4F									
TITANIUM DIOXIDE	(UNII: 15FIX9V	2JP)							
Product Charac	teristics								
Color	red		Score		no s	core			
Shape	ROUND (ROU	IND TABLET)	Size 10mm						
ilavor Imprint Code PH32						2			

Packaging										
#	ltem Code	Package Description	Marketing End Date							
1	NDC:0536- 1248-01	0 in 1 BOTTLE, PLASTIC; Type 0: Not a 10/22/2019 mbination Product								
2	NDC:0536-	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a	10/22/2019							
	1248-10	Combination Product								
	1248-10									
M		Information								
M			h Marketing Start Date	Marketing End Date						

Labeler - RUGBY LABORATORIES (079246066)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment								
Name	Address	ID/FEI	Business Operations					
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(0536-1248) , analysis(0536-1248) , pack(0536-1248) , label(0536-1248)					

Revised: 12/2022

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