

**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.*

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**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®**

**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



NDC 0536-1248-10  
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

1000 Tablets

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

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

**Drug Facts**

**Active ingredients (in each tablet)**

Docosate sodium 50 mg.....Stool softener  
Sennosides 8.6 mg.....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 lasts 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**

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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

\*This product is not manufactured or distributed by Avrio Health L.P., owner of the registered trademark Colace® 2-IN-1.

Distributed by:  
**RUGBY LABORATORIES**  
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Livonia, MI 48152  
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Rev. 10/19 R-111 Re-order No. 370792



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## STIMULANT LAXATIVE PLUS STOOL SOFTENER

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1248
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SENNOSIDES</b> (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

### Inactive Ingredients

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

### Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1248-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/22/2019	
2	NDC:0536-1248-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/22/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/22/2019	

**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

RUGBY LABORATORIES