STOOL SOFTENER PLUS STIMULANT LAXATIVE- docusate sodium 50 mg and sennosides 8.6 mg tablet, film coated
CARDINAL HEALTH, 110 DBA LEADER

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 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 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 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 15-30ºC (59-86ºF)

Inactive ingredients

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

Questions?

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

LEADER ™

NDC 70000-0526-1

Stool Softener +

Stimulant Laxative

Docusate Sodium, 50 mg

Sennosides, 8.6 mg

COMPARE TO

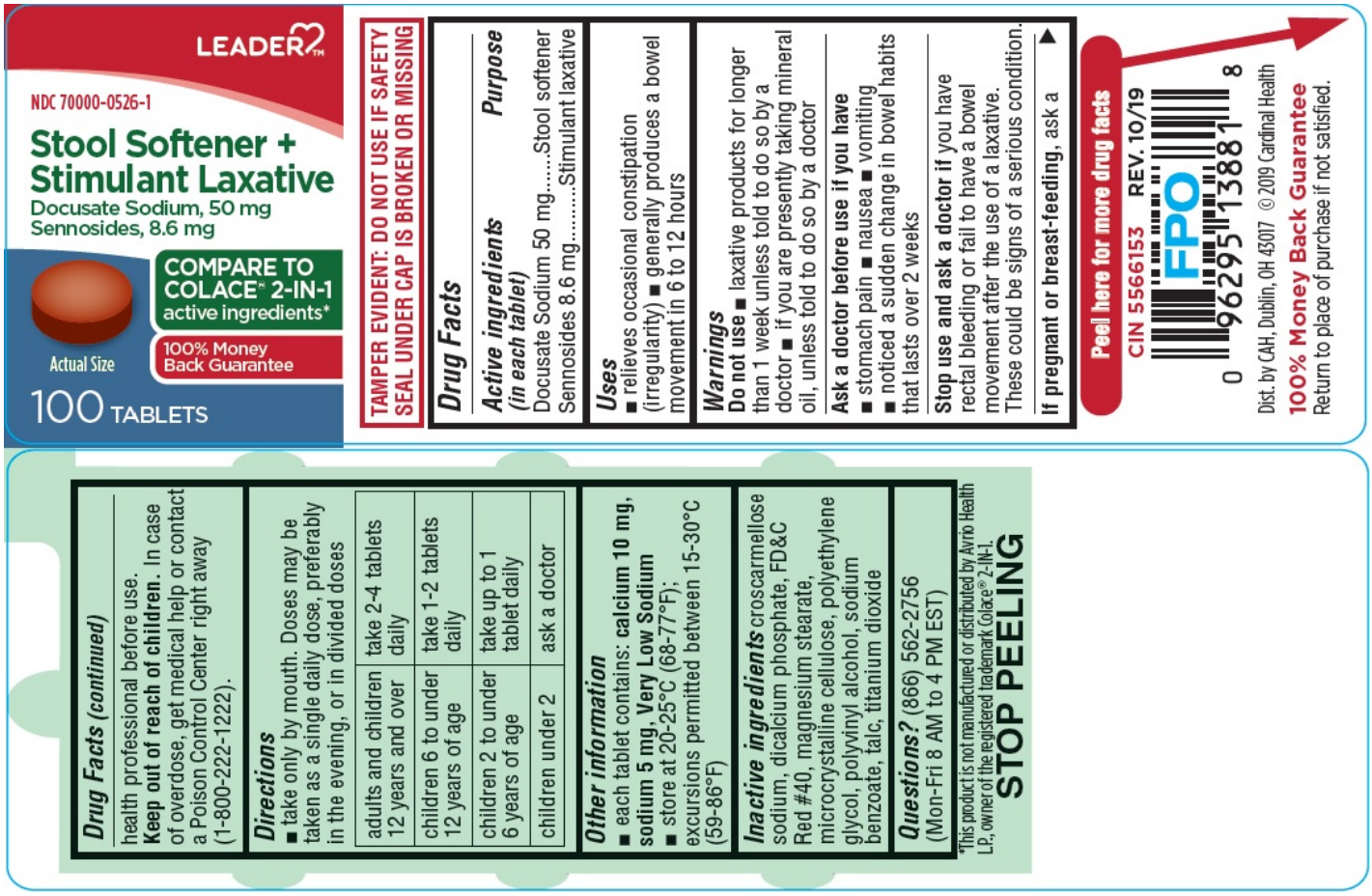
COLACE® 2-IN-1

active ingredients*

100% Money

Back Guarantee

100 TABLETS



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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0526
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: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0526-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/23/2019	

Labeler - CARDINAL HEALTH, 110 DBA LEADER (063997360)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(70000-0526) , analysis(70000-0526) , pack(70000-0526) , label(70000-0526)

Revised: 6/2021 CARDINAL HEALTH, 110 DBA LEADER