COLISTAT - docusate sodium tablet, film coated
Amvilab LLC

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 ingredient (in each tablet)

Docusate Sodium 100 mg

Purpose

Stool Softener

Uses

- for relief of occasional constipation (irregularity).This product generally produces a bowel movement within 12 to 72 hours.

Warnings

Do not use

- laxative products for longer than one week unless directed 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
- you fail to have a bowel movement after use

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a doctor before use.

Keep out of Reach of Children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

	Take 1 tablet as needed, not to exceed more than

Adults and children 12 years of age and older:	not to exceed more than 3 tablets daily, or as directed by a doctor.
Children under 12 years of age:	Consult a doctor before use.

Other information

- Each tablet contains: **Calcium 40 mg**
- Each tablet contains: **Sodium 10 mg**
- Store at room temperature.
- **Do not use if imprinted safety seal is broken or missing**

Inactive ingredients

Croscarmellose Sodium, Dicalcium Phosphate, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Silica, Sodium Benzoate, Stearic Acid.

Questions?

If you have any questions or comments, or to report an adverse event, please contact +1 404 256 8817

Principal Display Panel

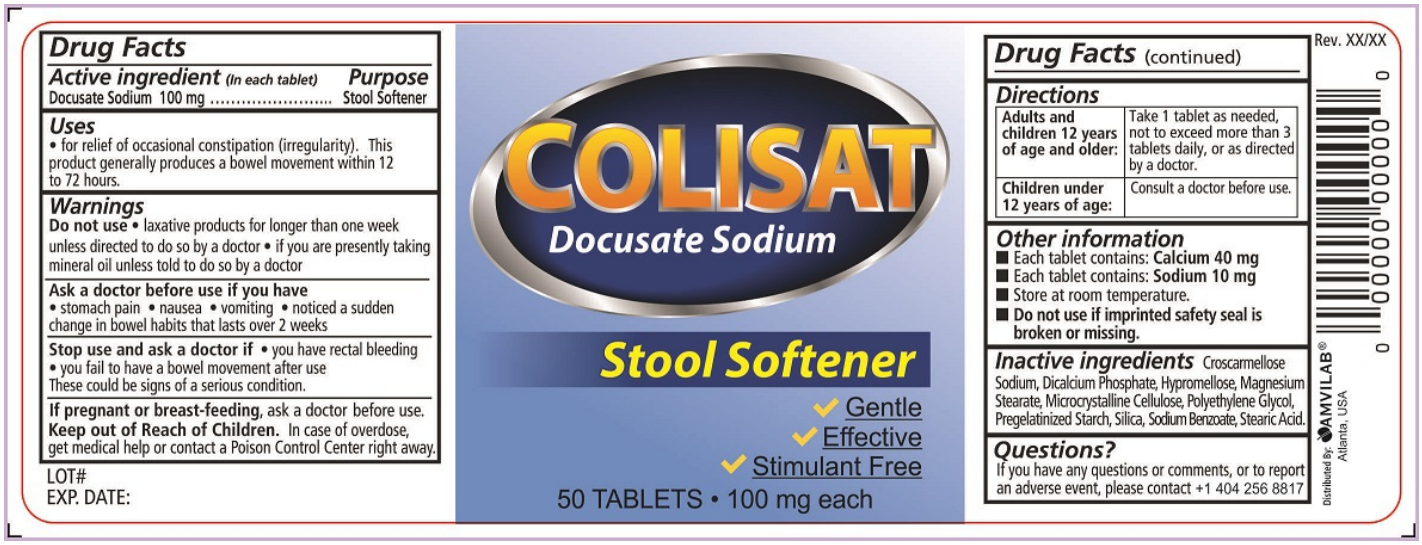
COLISTAT

Docusate Sodium

Stool Softener

- Gentle
- Effective
- Stimulant Free

50 TABLETS 100 mg each



COLISTAT

docusate sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69975-750
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND (Round Biconvex with bisect)	**Size**	11mm
Flavor		**Imprint Code**	GPI;S1

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69975-750-05	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/16/2015	

Labeler - Amvilab LLC (006092439)

Registrant - Gemini Pharmaceuticals, Inc. dba Plus Pharma (055942270)

Establishment

Name	Address	ID/FEI	Business Operations
Gemini Pharmaceuticals, Inc. dba Plus Pharma		055942270	manufacture(69975-750)

Revised: 7/2015 Amvilab LLC