

**COLISTAT PLUS - docusate sodium,sennosides 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.*

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**Drug Facts**

**Active ingredients (in each tablet)**

Docusate Sodium 50 mg

Sennosides 8.6 mg

**Purposes**

Docusate Sodium.....Stool Softener

Sennosides.....Laxative

**Uses**

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 6-12 hours

**Warnings**

**Do not use**

- if you are now taking mineral oil, unless directed by a doctor
- laxative products for longer than 1 week unless directed 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 a period of 2 weeks

**Stop use and ask a doctor if**

you have rectal bleeding or fail to have a bowel movement after use of a laxative.

These may indicate 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.

**Directions**

- take preferably at bedtime or as directed by a doctor
-

age	starting dose	maximum dose
adults and children 12 years and older	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

#### Other information

- Each tablet contains: **Calcium 20 mg**
- Each tablet contains: **Sodium 4 mg**
- Store at room temperature
- Keep lid tightly closed in a dry place
- **Do not use if imprinted seal under cap is broken or missing**
- **Tamper Evident: Do not use if sealed blister unit is broken or damaged**

#### Inactive ingredients

Croscarmellose Sodium, D and C Yellow #10, Dextrose, Dicalcium Phosphate, FD and C Yellow #6, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Silica, Sodium Benzoate, Stearic Acid, Titanium Dioxide.

#### Questions?

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

#### Principal Display Panel

COLISTAT PLUS

Stool Softener and Stimulant Laxative

- Effective
- Reliable
- Comfortable

60 TABLETS

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### Active ingredients

(in each tablet)

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Sennosides 8.6 mg.....Laxative

**Uses** relieves occasional constipation (irregularity) generally produces a bowel movement in 6-12 hours

### Warnings

**Do not use** if you are now taking mineral oil, unless directed by a doctor  
laxative products for longer than 1 week unless directed 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 a period of 2 weeks

**Stop use and ask a doctor if you have** rectal bleeding or fail to have a bowel movement after use of a laxative.  
These may indicate a serious condition.

Rev. 00/00

**Drug Facts** (continued on back)

**Do not use if imprinted safety seal under cap is broken or missing**



Lot#

Exp.



## ***Drug Facts*** (continued)

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.

***Directions*** take preferably at bedtime or as directed by a doctor

<b>age</b>	<b>starting dose</b>	<b>maximum dose</b>
adults and children 12 years and older	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	½ tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

## ***Other information***

Each tablet contains: **Calcium 20 mg**

Each tablet contains: **Sodium 4 mg**

Store at room temperature

Keep lid tightly closed in a dry place

## ***Inactive ingredients***

Croscarmellose Sodium, D&C Yellow #10, Dextrose, Dicalcium Phosphate, FD&C Yellow #6, Hypromellose, Magnesium

Stearate, Microcrystalline Cellulose,  
Polyethylene Glycol, Silica, Sodium  
Benzoate, Stearic Acid, Titanium Dioxide.

**Questions?** If you have any questions  
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Distributed By:  **AMVILAB**® | Atlanta, USA

## COLISTAT PLUS

docusate sodium,sennosides tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69975-850
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DEXTROSE (UNII: IY9XDZ35W2)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	orange	Score	no score
Shape	ROUND (Biconvex)	Size	10mm
Flavor		Imprint Code	G55
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69975-850-06	60 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(69975-850)