

## **DOCUZEN- sennosides 8.6mg and docusate sodium 50mg tablet**

**Village Pharma**

*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)**

Sennosides from Senna Concentrate 8.6mg

Docusate Sodium 50mg

#### **Purpose**

Laxative

Stool Softner

#### **Uses**

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

#### **Warnings**

##### **Do not use**

- laxative products for longer than 1 week unless directed by a doctor
- if you are taking mineral oils, 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
- you fail to have a bowel movement after the use of a laxative.

These may indicate a serious condition.

##### **If pregnant or breast feeding,**

ask a healthcare professional before use.

##### **Keep out of reach of children.**

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

## Directions

- take preferably at bedtime or as directed by a doctor

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age	starting dosage	maximum dosage
Adults and children 12 years and over	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

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## Other information

- each tablet contains **10 mg of calcium, sodium 5 mg**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

## Inactive ingredients

croscarmellose Sodium, D&C Yellow# 10, dicalcium phosphate, FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, sodium benzoate, talc & titanium dioxide.

## Questions or comments?

1-800-828-0464 Mon-Fri 8 AM to 4 PM

**VillagePharma**

**NDC 71574-700-60**

**DOCUZEN**

**Sennosides 8.6mg &**

**Docosate Sodium 50mg**

**60 TABLETS**

**Manufactured in the USA**

VillagePharma  
NDC 71574-700-60

# DOCUZEN

Sennosides 8.6mg &  
Docusate Sodium 50mg

60 TABLETS



<b>Drug Facts</b>	
<b>Active ingredients Purpose (in each tablet)</b>	Sennosides from Senna Concentrate 8.6mg.....Laxative Docusate Sodium 50mg.....Stool Softner
<b>Uses</b>	relieves occasional constipation (irregularity) generally produces a bowel movement in 6-12 hours
<b>Warnings</b>	<b>Do not use</b> laxative products for longer than 1 week unless directed by a doctor if you are taking mineral oil, unless directed by a doctor <b>Ask a doctor before use if you have</b> stomach pain nausea vomiting noticed a sudden change in bowel habits that continues over a period of 2 weeks
<b>Stop use and ask a doctor if</b>	you have rectal bleeding you fail to have a bowel movement after the use of a laxative.

**Peel here for more drug facts**

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Packaged For: VillagePharma, LLC Agoura Hills, CA 91301

These may indicate a serious condition. <b>If pregnant or breast feeding</b> , ask a healthcare professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center immediately.		
<b>Directions</b>	take preferably at bedtime or as directed by a doctor	
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Children under 2 years	ask a doctor	ask a doctor
<b>Other information</b>		
each tablet contains 10 mg of calcium, sodium 5 mg store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)		
<b>Inactive ingredients</b> croscarmellose sodium, D&C Yellow #10, dicalcium phosphate, FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, sodium benzoate, talc & titanium dioxide.		
<b>Questions or comments?</b> 1-800-828-0464 Mon - Fri 8 AM to 4 PM		

## DOCUZEN

sennosides 8.6mg and docusate sodium 50mg tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71574-700
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0JX) (SENNOSIDES - UNII:3FYP5M0JX)	SENNOSIDES	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

### Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

SODIUM BENZOATE (UNII: OJ245FE5EU)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	orange (ORANGE COLOR)	<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:71574-700-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/27/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/27/2018	

**Labeler** - Village Pharma (080749749)

**Registrant** - Village Pharma (080749749)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(71574-700) , pack(71574-700) , analysis(71574-700)

Revised: 11/2018

Village Pharma