

SEKOKOT-S - docuset sodium pill

Ajes Pharmaceuticals,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 Ingredients (in each tablet)

Docusate sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool Softner

Laxative

Keep Out of Reach of Children

In case of overdose, get medical help or contact

a Poison Control Center right away.

Uses

Relieves occasional constipation (irregularity)

Generally causes 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

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

Age

Starting dose

Maximum Dose

Adults and children 12 years of age or older 2 tablets once a day -

4 tablets twice a

children 6 to 12 years of age -
day

1 tablet once a day

2 tablets twice a

children 2 to 6 years of age

1/2 tablet once a day

1 tablet twice a day

children under 2 years of age

ask a doctor

Enter section

Ask a doctor before use if your have rectal bleeding or fail to have a bowel movement after use of a laxative. These may be signs of a serious condition

If pregnant or breast-feeding ask a health professional before use

Drug Facts	
Active Ingredient (in each tablet)	Purpose
Docusate sodium 50 mg.....	Stool Softener
Sennosides 8.6 mg.....	Laxative
Uses	
-relieves occasional constipation (irregularity) -generally causes 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 movements 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 be signs of a serious condition.	
If pregnant or breast-feeding ask a health professional before use	
Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center.	

Value/Pharma  NDC 42787-105-12

EASY
to swallow

Laxative/ Stool Softener

1000 TABLETS

50 MG

SENNA WITH DOCUSATE SODIUM TABLETS

Drug Facts Continued		
Directions -take preferably at bedtime or as directed by a doctor		
Age	Starting dose	Maximum dose
adults and children 12 years of age and older	2 tablets once a day	4 tablets twice a day
children 6 to 12 years of age	1 tablet once a day	2 tablets twice a day
children 2 to 6 years of age	½ tablet once a day	1 tablets twice a day
children under 2 years of age	ask a doctor	
Other Information		
-each tablet contains: sodium 6mg/ tablet VERY LOW SODIUM calcium 20mg/ tablet - store between 15° - 30° C (59° - 86° F) in well closed containers		
Inactive Ingredients Colloidal silicon dioxide, dibasic calcium phosphate dehydrate, FD&C Red # 40 Aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide,talc		

SENOKOT-S

docuset sodium pill

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42787-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg in 340 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg in 340 mg

Inactive Ingredients

Ingredient Name	Strength
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	orange (orange color)	Score	no score
Shape	ROUND (Pill)	Size	10mm
Flavor		Imprint Code	C18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42787-105-12	1 in 1 BOX		
1		50000 mg in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/01/2012	

Labeler - Ajes Pharmaceuticals,LLC (159945393)

Establishment

Name	Address	ID/FEI	Business Operations
Ajes Pharmaceuticals,LLC		159945393	manufacture(42787-105) , repack(42787-105) , relabel(42787-105)

Revised: 5/2014

Ajes Pharmaceuticals,LLC