# SENNA/DOCUSATE SODIUM- docusate sodium and sennosides tablet, film coated medsource pharmaceuticals

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.

-----

#### **DOK Plus Tablets**

## **Active Ingredients** (in each tablet)

Docusate Sodium 50 mg

Sennosides 8.6 mg

#### Purpose

Stool Softener

Stimulant Laxative

**Uses** relieves occasional constipation (irregularity). This product generally produces a bowel movement in 6 to 12 hours.

### Warnings

Ask a doctor before use if you have

- Stomach pain
- Nausea
- Vomiting
- A sudden change in bowel habits that lasts over a period of 2 weeks.

#### DO NOT USE

Laxative products for longer than 1 week unless directed by a doctor

If you are presently taking mineral oil, unless directed by a doctor

#### Ask Doctor/Pharmacist

Ask a doctor or pharmacist before use if you are presently taking mineral oil.

Take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided dose.

Age	Dosage
Adults and children	Take 2-4 tablets daily
12 years of age and older	·
Children 6 to under 12 years	Take 1-2 tablets daily
Children 2 to 6 years	Take up to 1 tablet daily
Children under 2 years	Do not use

#### **Generic Section**

#### Other information

- Each tablet contains: sodium 6 mg/tablet VERY LOW SODIUM
- Each tablet contains: calcium 20 mg/tablet.
- Store at 20° 25°C (68° -77°F); excursions permitted to 15°-30° (59°-86°F). [See USP Controlled Room Temperature]

**Inactive Ingredients:** Carnauba Wax, Colloidal Silicon Dioxide, Croscarmellose Sodium, Dibasic Calcium Phosphate Dihydrate, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, tapioca starch\*, tartaric acie\*, and titanium dioxide. \*may contain these ingredients.

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

#### Questions

Questions? To Report Serious Adverse Effects Call: (800)616-2471

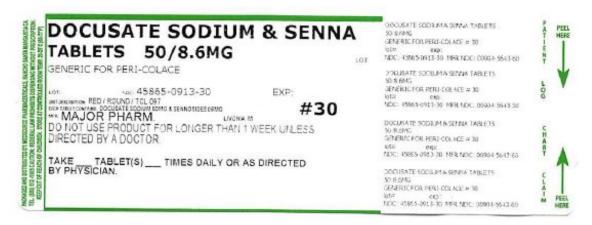
Distributed By:

Major® Pharmaceuticals

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152 USA

LHC51790417



#### SENNA/DOCUSATE SODIUM

docusate sodium and sennosides tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45865-913(NDC:0904-5643)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX)	SENNOSIDES	8.6 mg	
DO CUSATE SO DIUM (UNII: F05Q2T2JA0) (DO CUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0 EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		

DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics					
Color	red	Score	no score		
Shape	ROUND	Size	10 mm		
Flavor		Imprint Code	TCL097		
Contains					

ı	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:45865-913-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	0 1/0 1/20 10		

# **Labeler** - medsource pharmaceuticals (833685915)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
medsource pharmaceuticals		833685915	repack(45865-913)	

Revised: 12/2018 medsource pharmaceuticals