

## **SENNOSIDES, DOCUSATE SODIUM- sennosides, docusate sodium tablet, film coated**

### **Major 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.*

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### **3052C-Major**

#### ***Drug Facts***

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

Docusate sodium 50 mg

Sennosides 8.6 mg

##### ***Purposes***

Stool softener

Stimulant laxative

##### ***Uses*** □

- for overnight relief from occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

##### ***Do not use*** □

- laxative products for longer than 1 week unless directed by a doctor □
- if you are now taking mineral oil, 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 lasts 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.

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

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adults and children 12 years and older

children 6 to under 12 years of age

children 2 to under 6 years of age

take 2-4 tablets daily

take 1-2 tablets daily

take up to 1 tablet daily

**Other information**

- **each tablet contains:** calcium 11 mg
- **each tablet contains:** sodium 4 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

croscarmellose sodium, dicalcium phosphate, FD&C blue #1 lake, FD&C red #40 lake, FD&C yellow #6 lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide and triacetin.

**Questions or comments?****Call 1 (800) 616-2471****TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**Distributed by: **MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA

†This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace®2-IN-1.

**MAJOR®**

NDC 0904-6723-60

A Stimulant Laxative &amp; Stool Softener For Use in the Management of Temporary Constipation

**DOK™ PLUS**

(Docusate Sodium 50 mg and Sennosides 8.6 mg)

Compare to the active ingredients in **COLACE®2-IN-1†****100 Tablets**

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Re-order No. 700908 Rev. 07/18 M-29 12988-07-18

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### Drug Facts

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Sennosides 8.6 mg... Stimulant laxative

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■ generally produces bowel movement  
in 6 to 12 hours

#### Warnings

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longer than 1 week unless directed by a  
doctor ■ if you are now taking mineral  
oil, unless directed by a doctor

#### Ask a doctor before use if you have

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**Drug Facts** (continued on back)



## INSIDE OF LABEL

### Drug Facts (continued)

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rectal bleeding or fail to have a bowel  
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professional before use. **Keep out of reach  
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children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily
children under 2	ask a doctor

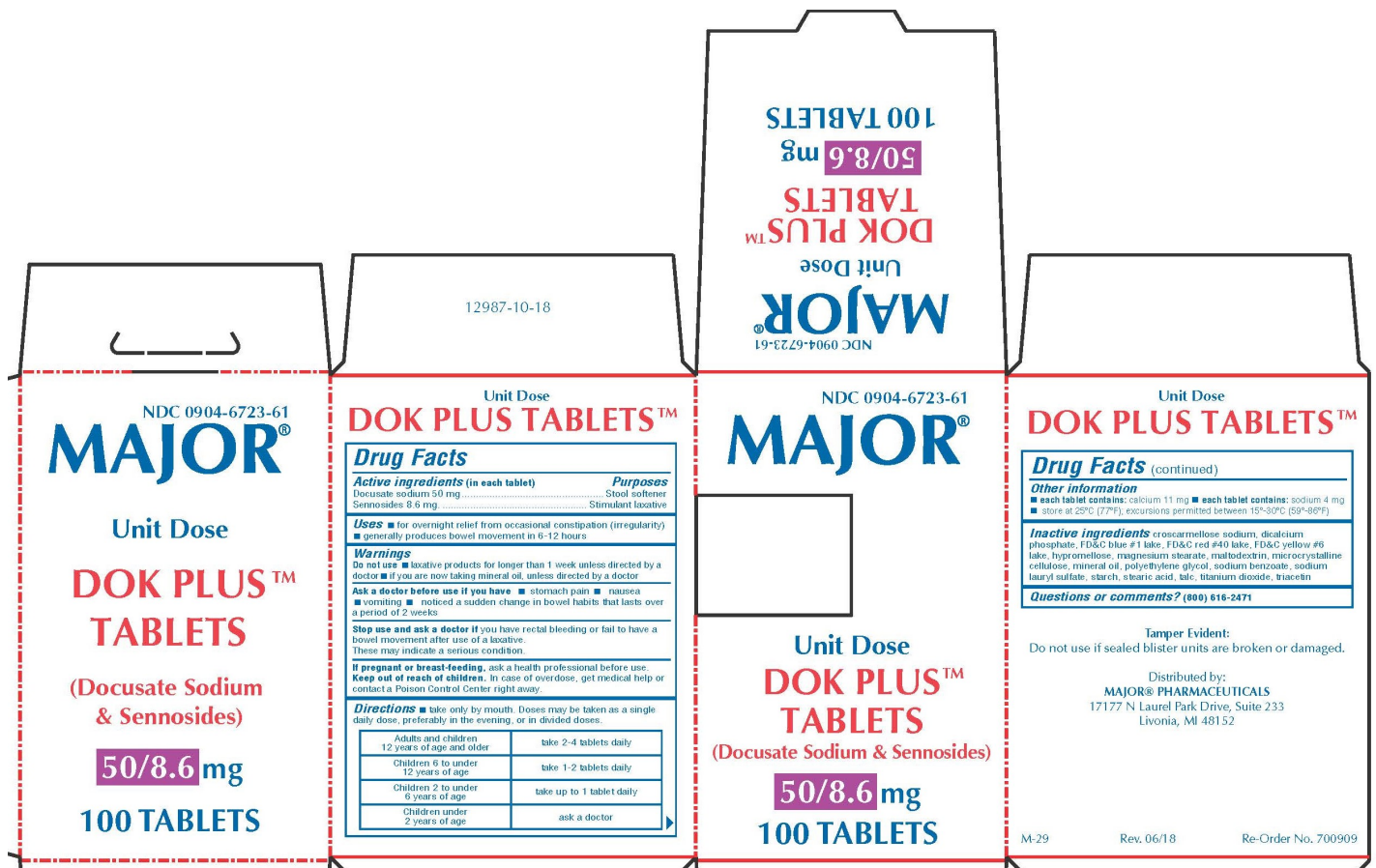
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**Inactive ingredients** croscarmellose  
sodium, dicalcium phosphate, FD&C blue #1  
lake, FD&C red #40 lake, FD&C yellow #6 lake,  
hypromellose, magnesium stearate,  
maltodextrin, microcrystalline cellulose,  
mineral oil, polyethylene glycol, sodium  
benzoate, sodium lauryl sulfate, starch, stearic  
acid, talc, titanium dioxide and triacetin.

#### Questions or comments?

Call 1 (800) 616-2471



## SENNOSIDES, DOCUSATE SODIUM

sennosides, docusate sodium tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6723
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
SENNOSIDES (UNII: 3FYP5M0IUX) (SENNOSIDES - UNII:3FYP5M0IUX)	SENNOSIDES	8.6 mg

### Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

MAGNESIUM STEARATE (UNII: 70097M6I30)
MALTO DEXTRIN (UNII: 7CVR7L4A2D)
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)
HYPROMELLOSES (UNII: 3NXW29V3WO)
STARCH, CORN (UNII: O8232NY3SJ)
STEARIC ACID (UNII: 4ELV7Z65AP)
FD&C RED NO. 40 (UNII: WZB9127XOA)
LIGHT MINERAL OIL (UNII: N6K5787QVP)
TALC (UNII: 7SEV7J4R1U)
TRIACETIN (UNII: XHX3C3X673)

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	CPC;490
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6723-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2019	12/31/2021
2	NDC:0904-6723-61	10 in 1 BOX	03/07/2019	04/30/2022
2		10 in 1 BLISTER PACK; 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	01/31/2019	04/30/2022

**Labeler - Major Pharmaceuticals (191427277)**