DOK- docusate sodium tablet
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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Active ingredient

Docusate Sodium 100 mg

Purpose

Stool Softener Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Ask a doctor before use if you

- have stomach pain, nausea or vomiting
- have a sudden change in bowel habits that persists over a period of 2 weeks
- are presently taking mineral oil

Stop use and ask a doctor if

- you need to use a laxative longer than 1 week
- you have rectal bleeding or fail to have a bowel movement. These could be signs of a serious condition.

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

Keep out of reach of children

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

Directions

- adults and children 12 years and older:take 1 tablet as needed, not to exceed 3 tablets daily, or as directed by a doctor
- children under 12: consult a doctor
- tablets may be swallowed whole or crushed and mixed with food

Other information

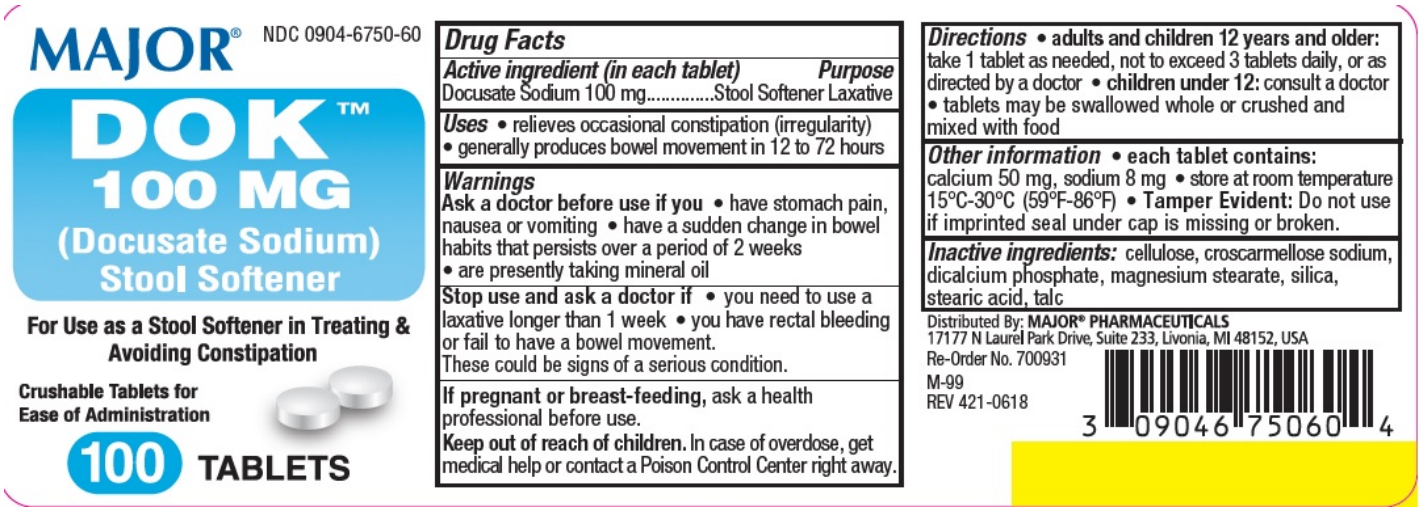
- **each tablet contains:** calcium 50 mg, sodium 8 mg
- package not child resistant
- store at room temperature 15°C-30°C (59°F-86°F)

- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken

Inactive ingredients

cellulose, croscarmellose sodium, dicalcium phosphate, magnesium stearate, silica, stearic acid, talc

PACKAGE LABEL



DOK

docusate sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6750
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	**Score**	no score

Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	GC422
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6750-60	100 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	06/01/2018	

Labeler - MAJOR PHARMACEUTICALS (191427277)

Registrant - Geri-Care Pharmaceuticals, Corp (611196254)

Revised: 11/2018 MAJOR PHARMACEUTICALS