

GERI-KOT - standardized senna concentrate tablet
DOH CENTRAL PHARMACY

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.

Active ingredient (in each tablet)

Sennosides 8.6 mg

Purpose

Laxative

Uses

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

Warnings

Do not use for more than 1 week unless directed by a doctor.

Ask a doctor before use if you

- have abdominal pain, nausea or vomiting
- have noticed a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor if

- you have no bowel movement within 12 hours
- you have rectal bleeding

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

Directions

- do not exceed 8 tablets in 24 hours

Age	Starting Dose	Maximum Dose
adults and children 12 years of age and older	2 tablets once a day preferably at bedtime; increase as needed, or as directed by a doctor	4 tablets in the morning and 4 tablets at bedtime
children under 12 years	ask a doctor	

Other information

- **each tablet contains:** calcium 20 mg

- store at room temperature

This Product was Repackaged By:

DOH CENTRAL PHARMACY
 104 HAMILTON PARK DR # 2
 TALLAHASSEE, FL 32304
 USA

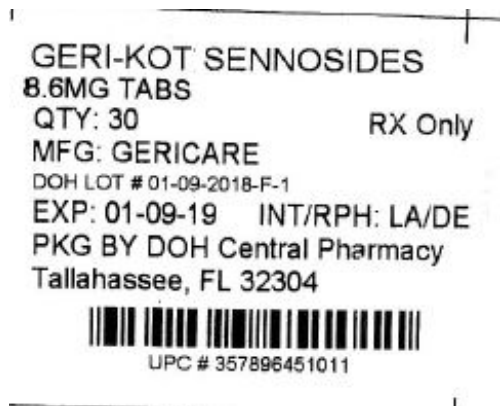
Inactive ingredients

cellulose, croscarmellose sodium, dicalcium phosphate, hypromellose, magnesium silicate, magnesium stearate, mineral oil, PEG.

PACKAGE LABEL

Label Image for **53808-1110**

8.6mg



GERI-KOT			
standardized senna concentrate tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53808-1110(NDC:57896-451)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)		SENNOSIDES	8.6 mg
Inactive Ingredients			
Ingredient Name			Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)			
MAGNESIUM SILICATE (UNII: 9B9691B2N9)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	BROWN (light brown)	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	1122
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-1110-1	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	01/09/2018	

Labeler - DOH CENTRAL PHARMACY (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
DOH CENTRAL PHARMACY		829348114	repack(53808-1110)

Revised: 1/2019

DOH CENTRAL PHARMACY