SANKAIJO- docusate sodium, sennosides tablet
Sato Pharmaceutical Co., Ltd.

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.

Sankaijo

Active ingredients (in each tablet)
Docusate sodium 8.33mg
Sennosides 1.36mg

Purposes
Docusate sodium Stool softener laxative
Sennosides Stimulant laxative

Uses
■for the relief of occasional constipation (irregularity)
■generally produces bowel movement in 6 to 12 hours

Warnings

Do not use laxative products for a period longer than 1 week unless directed by a doctor

Ask a doctor before use if you have
■abdominal pain, nausea, or vomiting
■noticed a sudden change in bowel habits that persists over a period of 2 weeks

Ask a doctor or pharmacist before useif you are presently taking mineral oil

Stop use and ask a doctor if
■you have rectal bleeding or failure to have a bowel movement after use of a laxative (may indicate a serious condition)

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

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

Frequent or prolonged use of this preparation may result in dependence on laxatives.

Directions
adults and children 12 years and older - take 6 to 12 tablets once or twice a day
children 6 to under 12 years - take 5 to 7 tablets once or twice a day
children 2 to under 6 years - take 3 to 5 tablets once or twice a day
children under 2 years - consult a doctor
■once or twice daily, preferably morning and evening, when needed or as directed by a doctor
■start initial dosage with minimum dose, then adjust it to suit to bowel condition

Other information
■each tablet contains calcium 5 mg

Inactive ingredients caramel, carmellose calcium, cinnamon, dibasic calcium phosphate, FDandC Blue No. 2, fennel, hydroxypropyl methylcellulose, magnesium stearate, mentha oil, microcrystalline cellulose, moutan bark, pharbitis seed, polyoxyethylene (105) polyoxypropylene (5) glycol, silicon dioxide, simethicone, synthetic iron oxide, talc

SANKAIJO

docusate sodium, sennosides tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-404
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	8.33 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	1.36 mg

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FENNEL (UNII: 557II4LLC3)	
HYPROMELLOSE 2910 (15000 MPA.S) (UNII: 288VBX44JC)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PAEONIA SUFFRUTICOSA ROOT BARK (UNII: BUG255FE7X)	
IPOMOEA NIL SEED (UNII: I85W45B4WB)	
PEG/PPG-105/5 COPOLYMER (UNII: 52901V8XAR)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	brown (greenish brown)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor	CINNAMON, MENTHOL	**Imprint Code**	SATO;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-404-01	1 in 1 CARTON	12/20/2002	
1		150 in 1 BOTTLE; 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	12/20/2002	

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-404) , label(49873-404) , pack(49873-404)

Revised: 12/2019 Sato Pharmaceutical Co., Ltd.