SENNA PLUS- sennosides and docusate sodium tablet
Bryant Ranch Prepack

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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gc 455t (458)

Active ingredient (in each tablet)

Docusate Sodium 50 mg
Sennosides 8.6 mg

Purpose

Stool softener

Laxative

Uses

- relieves occasional constipation (irregularity)
- this product generally produces a 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
- are taking mineral oil
- 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
- rectal bleeding
- these could 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, sodium 6 mg
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.
- store at room temperature

Inactive ingredients

cellulose, croscarmellose sodium, dicalcium phosphate, FD&C yellow #6, hypromellose, magnesium stearate, PEG, sodium benzoate, stearic acid, titanium dioxide. May also contain D&C yellow #10, FD&C yellow #5 (tartrazine), magnesium silicate, mineral oil, silica, sodium lauryl sulfate, starch, triacetin, wax.

HOW SUPPLIED

NDC: 71335-1181-1: 30 Tablets in a BOTTLE

NDC: 71335-1181-2: 120 Tablets in a BOTTLE

NDC: 71335-1181-3: 60 Tablets in a BOTTLE

NDC: 71335-1181-4: 90 Tablets in a BOTTLE

NDC: 71335-1181-5: 100 Tablets in a BOTTLE

NDC: 71335-1181-6: 28 Tablets in a BOTTLE

NDC: 71335-1181-7: 56 Tablets in a BOTTLE

NDC: 71335-1181-8: 14 Tablets in a BOTTLE

NDC: 71335-1181-9: 20 Tablets in a BOTTLE

Docusate/ Sennosides 50/8.6 mg Tablet

SENNA PLUS

sennosides and docusate sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-1181(NDC:57896-458)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (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: 3WQ0SDW1A)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	TCL081
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-1181-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2021	
2	NDC:71335-1181-2	120 in 1 BOTTLE; Type 0: Not a Combination Product	02/05/2020	
3	NDC:71335-1181-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	
4	NDC:71335-1181-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2022	
5	NDC:71335-1181-5	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2019	
6	NDC:71335-1181-6	28 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2019	
7	NDC:71335-1181-7	56 in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2022	
8	NDC:71335-1181-8	14 in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2022	
9	NDC:71335-1181-9	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2000	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1181) , RELABEL(71335-1181)

Revised: 2/2022