**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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**0490C-Major**

***Drug Facts***

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

Docusate sodium 50 mg

Sennosides 8.6 mg

***Purposes***

Stool softener

Laxative

***Uses***

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

**Do not use** 

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

**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 preferably at bedtime or as directed by a doctor

| age | starting dosage | maximum dosage |
|---|---|---|
| adults and children<br>12 years of age or over | 2 tablets<br>once a day | 4 tablets<br>twice a day |
| children 6 to under<br>12 years of age | 1 tablet<br>once a day | 2 tablets<br>twice a day |

| | | |
|---|---|---|
| children 2 to under 6 years of age | 1/2 tablet once a day | 1 tablets twice a day |
| children under 2 years of age | ask a doctor | ask a doctor |

***Other information***

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

croscarmellose sodium, dicalcium phosphate, FD&C yellow #5 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, triacetin

*contains FD&C yellow #5 lake (tartrazine) as a color additive.

***Questions or comments?***

**(800) 616-2471**

**Tamper Evident:** Do not use if sealed blister units are broken or damaged.

Product color may slightly vary due to natural changes of ingredients.

Distributed by:

**MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

NDC 0904-6724-61

**MAJOR**

Unit Dose

**SENNA PLUS TABLETS**
(Stadardized Senna Concentrate & Docusate Sodium)

8.6/50 mg

**100 Tablets**


# SENNOSIDES,DOCUSATE SODIUM

sennosides,docusate sodium tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0904-6724 |
| **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** |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE** (UNII: O7TSZ97GEP) | |

| | |
|---|---|
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | CPC;490 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0904-6724-61 | 10 in 1 BOX | 03/14/2019 | |
| **1** | | 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 | 03/14/2019 | |

## Labeler - Major Pharmaceuticals (191427277)

Revised: 5/2020 Major Pharmaceuticals