#### STIMULANT LAXATIVE PLUS STOOL SOFTENER- docusate sodium 50 mg and sennosides 8.6 mg tablet, film coated ATLANTIC BIOLOGICALS CORP.

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# **Drug Facts**

# Active Ingredients (in each tablet)

Docusate Sodium 50 mg

Sennosides 8.6 mg

# Purpose

Stool softener

Stimulant laxative

#### Uses

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

# Warnings

# Do not use

- laxative products for longer than 1 week unless told to do so by a doctor
- if you are presently taking mineral oil, unless told to do so 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 2 weeks

# Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after the use of a laxative.

These could be sings 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 (1-800-222-1222).

# Directions

• take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses

| adults and children 12 years   | take 2-4 tablets   |
|--------------------------------|--------------------|
| and over                       | daily              |
| children 6 to under 12 years   | take 1-2 tablets   |
| of age                         | daily              |
| children 2 to under 6 years of | take upto 1 tablet |
| age                            | daily              |
| children under 2               | ask a doctor       |

# Other information

- each tablet contains: calcium 10 mg, sodium 5 mg, Very Low Sodium
- store at 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)

# Inactive ingredients

croscarmellose sodium, dicalcium phosphate, FD&C Red #40, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium benzoate, talc, titanium dioxide

# **Questions or comments?**

1-800-645-2158

# **DISTRIBUTED BY:**

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

NDC 17856-1248-01

Compare to the

active ingredients

in Colace<sup>®</sup> 2-IN-1\*

Stimulant

Laxative

**Plus Stool Softener** 

Docusate Sodium, 50 mg

Sennosides, 8.6 mg

50 mg/ 8.6 mg

**100 TABLETS** 

#### 17856-1248-01 SENNOSIDES/ UDOSE DOCUSATE SODIUM DELIVERS 1TAB/50mg/8.6mg

See package insert for indications and dosage schedule

Each tablet contains: Docusate Sodium(50mg), Sennosides(8.6mg), Calcium(10mg), and Sodium(≤5mg). Store at 20-25°C(68-77°F); excursion permitted between 15-30°C(59-86°F). \*\*Keep this and all Medications out of the reach of children\*\*

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Call to Reorder: 800.509.7592 Rev.08/21

# STIMULANT LAXATIVE PLUS STOOL SOFTENER

docusate sodium 50 mg and sennosides 8.6 mg tablet, film coated

| Product Information   |                            |                    |                     |            |  |
|---|----------------------------|--------------------|---------------------|------------|--|
| Product Type  | HUMAN OTC DRUG             | Item Code (Source) | NDC:17856-1248(NDC: | 0536-1248) |  |
| Route of Administration   | ORAL                       |                    |                     |            |  |
|   |                            |                    |                     |            |  |
| Active Ingredient/Active  | Moiety                     |                    |                     |            |  |
|   | edient Name                |                    | Basis of Strength   | Strength   |  |
|   |                            |                    | SENNOSIDES          | 8.6 mg     |  |
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) |                            |                    | DOCUSATE SODIUM     | 50 mg      |  |
|   |                            |                    |                     |            |  |
| Inactive Ingredients  |                            |                    |                     |            |  |
|   | Ingredient N               | ame                | 5                   | Strength   |  |
| CROSCARMELLOSE SODIUM (UN                                       | II: M28OL1HH48)            |                    |                     |            |  |
| CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)        |                            |                    |                     |            |  |
| FD&C RED NO. 40 (UNII: WZ B9127XOA)                             |                            |                    |                     |            |  |
| MAGNESIUM STEARATE (UNII: 700                                   | 097M6I30)                  |                    |                     |            |  |
| CELLULOSE, MICROCRYSTALLIN                                      | <b>E</b> (UNII: OP1R32D61U | ))                 |                     |            |  |

|                                     | LYETHYLENE GL                                    | YCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)  |      |                                    |                       |  |
|-------------------------------------|--|---|------|------------------------------------|-----------------------|--|
| PO                                  | LYVINYL ALCOH                                    | OL, UNSPECIFIED (UNII: 532B59J990)  |      |                                    |                       |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)  |  |   |      |                                    |                       |  |
| TALC (UNII: 7SEV7J4R1U)             |  |   |      |                                    |                       |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) |  |   |      |                                    |                       |  |
|                                     |  |   |      |                                    |                       |  |
|                                     |  |   |      |                                    |                       |  |
| Pr                                  | oduct Chara                                      | cteristics  |      |                                    |                       |  |
| Co                                  | lor  | red   | S    | core                               | no score              |  |
| Sh                                  | аре  | ROUND (ROUND TABLET)  | S    | ize                                | 10mm                  |  |
| Fla                                 | vor  |   | In   | nprint Code                        | PH32                  |  |
| Co                                  | ntains   |   |      |                                    |                       |  |
|                                     |  |   |      |                                    |                       |  |
|                                     |  |   |      |                                    |                       |  |
|                                     |  |   |      |                                    |                       |  |
| Pa                                  | ickaging   |   |      |                                    |                       |  |
|                                     | ickaging<br>Item Code                            | Package Description   | Ĩ    | Marketing Start<br>Date            | Marketing End<br>Date |  |
| #                                   | Item Code  | Package Description   |      | -                                  | -                     |  |
| #                                   | Item Code<br>NDC:17856-<br>1248-1                | 2 .   |      | Date                               | -                     |  |
| #<br>1                              | Item Code<br>NDC:17856-<br>1248-1                | 100 in 1 BOX, UNIT-DOSE<br>1 in 1 POUCH; Type 0: Not a Combination  |      | Date                               | -                     |  |
| #<br>1                              | Item Code<br>NDC:17856-<br>1248-1                | 100 in 1 BOX, UNIT-DOSE<br>1 in 1 POUCH; Type 0: Not a Combination  |      | Date                               | -                     |  |
| #<br>1<br>1                         | Item Code<br>NDC:17856-<br>1248-1                | 100 in 1 BOX, UNIT-DOSE<br>1 in 1 POUCH; Type 0: Not a Combination  |      | Date                               | -                     |  |
| #<br>1<br>1                         | Item Code<br>NDC:17856-<br>1248-1                | 100 in 1 BOX, UNIT-DOSE<br>1 in 1 POUCH; Type 0: Not a Combination<br>Product   | 05/0 | Date                               | -                     |  |
| #<br>1<br>1                         | Item Code NDC:17856- 1248-1 arketing I Marketing | 100 in 1 BOX, UNIT-DOSE<br>1 in 1 POUCH; Type 0: Not a Combination<br>Product<br>nformation<br>Application Number or Monogr<br>Citation | 05/( | Date<br>09/2024<br>Marketing Start | Date<br>Marketing End |  |

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

**Registrant -** ATLANTIC BIOLOGICALS CORP. (047437707)

| Establishment       |         |           |                            |  |  |
|---------------------|---------|-----------|----------------------------|--|--|
| Name                | Address | ID/FEI    | <b>Business Operations</b> |  |  |
| UNIT DOSE SOLUTIONS |         | 360804194 | repack(17856-1248)         |  |  |

Revised: 5/2024

ATLANTIC BIOLOGICALS CORP.