# HEALTH SENSE SENNO- sennosides tablet Prime Marketing, LLC

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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#### health sense 451

# **Active ingredient (in each tablet)**

Sennosides 8.6 mg

### **Purpose**

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 one 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 two 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                     | Age Starting Dose                              |                          |
|-------------------------|--|--------------------------|
| adults and children 12  | 7  | 4 tablets in the morning |
| years of age and older  | increase as needed, or as directed by a doctor | and 4 tablets at bedtime |
| children under 12 years | ask a doctor                                   |                          |

#### Other information

- each tablet contains: calcium 20 mg
- store at room temperature

### **Inactive ingredients**

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

# **Package Label**

NDC 62107-031-01

#### **Health Sense**

#### Senno

tablets

Natural Vegetable Laxative

Compare to the Active Ingredient in Senokot\*

100 Tablets

8.6 mg Each

| Drug Facts  | NDC 62107-031-01              |
|---|-------------------------------|
| Active ingredient (in each tablet) Purpose                            | #Health Sense                 |
| Sennosides, 8,6 mgLaxative  | Of reconstructing             |
| Uses • relieves occasional constipation (irregularity) • this product | CT Th                         |
| generally produces a bowel movement in 6 to 12 hours                  | 101010 O                      |
| Warnings  | PVIVII                        |
| Do not use for more than one week unless directed by a doctor.        | Senno                         |
| Ask a doctor before use if you . have abdominal pain, nausea or       |                               |
| vomiting . have noticed a sudden change in bowel habits that lasts    | tablets                       |
| over two weeks  |                               |
| Stop use and ask a doctor if . you have no bowel movement             | Natural Vegetable<br>Laxative |
| within 12 hours • you have rectal bleeding                            | Total de regetable            |
| These could be signs of a serious condition.                          | Laxative                      |
| f pregnant or breast-feeding, ask a health professional before use.   | Compare to the Active         |
| Keep out of reach of children. In case of overdose, get medical help  | Compare to the Active         |
|   |                               |

100 TABLETS 8.6 mg Each

Ingredient in Senokot®\*

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

| Age  | Starting Dose        |  | Maximum Dose   |  |
|--|----------------------|--|--|--|
| Adults and<br>children 12<br>years of age<br>and older | preferab<br>increase | ls once a day<br>ly at bedtime;<br>as needed, or<br>ed by a doctor | 4 tablets in the<br>morning and<br>4 tablets at<br>bedtime |  |
| Children under   | r 12 years           | Ask a doctor   | 93.50 posperiole 99  |  |

Other information • each tablet contains: calcium 20 mg • store at room temperature

Inactive ingredients: cellulose, croscarme ose sodium, dicalcium phosphate, hypromellose, magnesium silicate, magnesium stearate, mineral oil, PEG

\*This product is not manufactured or distributed by the owner of the registered trademark SENOKOT®. REV 1212

Dist.by: Prime Marketing, 1775 John R Road, Troy, MI 48083

#### **HEALTH SENSE SENNO**

62107<sup>||</sup>03101**||**|

or contact a Poison Control Center right away.

sennosides tablet

#### **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:62107-031 **Route of Administration** ORAL

| Active Ingredient/Active Moiety                                   |                   |          |  |
|---|-------------------|----------|--|
| Ingredient Name   | Basis of Strength | Strength |  |
| SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX) | SENNOSIDES        | 8.6 mg   |  |
|   |                   |          |  |

| Inactive Ingredients                                       |          |  |  |
|--|----------|--|--|
| Ingredient Name  | Strength |  |  |
| CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)            |          |  |  |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)                  |          |  |  |
| CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J) |          |  |  |
| MAGNESIUM SILICATE (UNII: 9B9691B2N9)                      |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                      |          |  |  |
| MINERAL OIL (UNII: T5L8T28FGP)                             |          |  |  |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)                    |          |  |  |
| HYPROMELLOSES (UNII: 3NXW29V3WO)                           |          |  |  |

| Product Characteristics |                     |              |          |
|-------------------------|---------------------|--------------|----------|
| Color                   | brown (light brown) | Score        | no score |
| Shape                   | ROUND               | Size         | 9 mm     |
| Flavor                  |                     | Imprint Code | 1122     |
| Contains                |                     |              |          |

| Packaging          |                     |                      |                    |
|--------------------|---------------------|----------------------|--------------------|
| # Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:62107-031-01 | 100 in 1 BOTTLE     |                      |                    |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part334                                  | 11/0 1/20 0 5        |                    |  |
|                         |  |                      |                    |  |

# Labeler - Prime Marketing, LLC (071371194)

# Registrant - Geri-Care Pharmaceutical Corp (611196254)

| Establishment                   |         |           |                            |
|---------------------------------|---------|-----------|----------------------------|
| Name                            | Address | ID/FEI    | <b>Business Operations</b> |
| Geri-Care Pharmaceuticals, Corp |         | 611196254 | repack(62107-031)          |

Revised: 12/2014 Prime Marketing, LLC