#### GOOD NEIGHBOR PHARMACY LOPERAMIDE HYDROCHLORIDE- loperamide hcl suspension Amerisource Bergen

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### Amerisource Bergen Loperamide Hydrochloride Oral Suspension Drug Facts

#### Active ingredient (in each 7.5 mL)

Loperamide HCl 1 mg

#### Purpose

Anti-diarrheal

#### Use

controls symptoms of diarrhea, including Travelers' Diarrhea

#### Warnings

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

#### Do not use

if you have bloody or black stool

#### Ask a doctor before use if you have

- fever
- mucus in the stool
- a history of liver disease

## Ask a doctor or pharmacist before use if you are

taking antibiotics

#### When using this product

• tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

#### Stop use and ask a doctor if

- symptoms get worse
- diarrhea lasts for more than 2 days
- you get abdominal swelling or bulging.

These may 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. (1-800-222-1222)

#### Directions

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- shake well before using
- only use attached measuring cup to dose product

| adults and<br>children<br>12 years and<br>over | 30 mL (6 tsp) after the first loose stool; 15 mL (3 tsp) after each subsequent loose stool; but no more than 60 mL (12 tsp) in 24 hours     |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| children 9-11<br>years<br>(60-95 lbs)          | 15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 45 mL (9 tsp) in 24 hours |
| children 6-8<br>years<br>(48-59 lbs)           | 15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 30 mL (6 tsp) in 24 hours |
| children under<br>6 years<br>(up to 47 lbs)    | ask a doctor                                                                                                                                |

#### Other information

- each 30 mL (6 tsp) contains: sodium 15 mg
- store between 20-25°C (68-77°F)
- see side panel for lot number and expiration date

#### **Inactive ingredients**

anhydrous citric acid, carboxymethylcellulose sodium, D&C yellow no. 10, FD&C blue no. 1, glycerin, microcrystalline cellulose, natural and artificial mint flavor, propylene glycol, purified water, simethicone, sodium benzoate, sucralose, titanium dioxide, xanthan gum

#### Questions or comments?

1-800-719-9260

# Package/Label Principal Display Panel

Compare to Imodium® A-D active ingredient Loperamide Hydrochloride Oral Suspension anti-diarrheal Controls the Symptoms of Diarrhea mint flavor 1 mg loperamide hydrochloride per 7.5 mL



| <i>Drug Facts</i> (continued)                                                                                                                                                           | Drug Facts (continued)                                                                                                                             |                                                                                                                                                      |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Ask a doctor before use if you have ■ fever<br>■ mucus in the stool ■ a history of liver disease                                                                                        |                                                                                                                                                    | ht away. (1-800-222-1222)                                                                                                                            |  |
| Ask a doctor or pharmacist before use if you are taking antibiotics                                                                                                                     | Directions ■ drink plenty of clear fluids to<br>help prevent dehydration caused by diarrhea<br>■ find right dose on chart. If possible, use weight |                                                                                                                                                      |  |
| When using this product matter tiredness,<br>drowsiness or dizziness may occur. Be careful<br>when driving or operating machinery.                                                      | to dose; otherwise                                                                                                                                 | e use age. ■ shake well<br>only use attached measuring                                                                                               |  |
| Stop use and ask a doctor if<br>■ symptoms get worse<br>■ diarrhea lasts for more than 2 days<br>■ you get abdominal swelling or bulging.<br>These may be signs of a serious condition. |                                                                                                                                                    | 30 mL (6 tsp) after the first loose<br>stool; 15 mL (3 tsp) after each<br>subsequent loose stool; but no more<br>than 60 mL (12 tsp) in 24 hours     |  |
| If pregnant or breast-feeding, ask a health<br>professional before use.<br>Keep out of reach of children. In case of<br>overdose, get medical help or contact a Poison                  | children 9-11 years<br>(60-95 lbs)                                                                                                                 | 15 mL (3 tsp) after the first loose<br>stool; 7.5 mL (1 1/2 tsp) after each<br>subsequent loose stool; but no more<br>than 45 mL (9 tsp) in 24 hours |  |

|                                                                                                       | JUUU                                                                                |                                                                                                                                                  | $\left  \right\rangle$ |
|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| children 6-8 years15 mL (3 tsp) after the first<br>loose stool; 7.5 mL (1 1/2 tsp)                    |                                                                                     | Drug Facts (continued)<br>■ see side panel for lot number and<br>expiration date                                                                 |                        |
|                                                                                                       | after each subsequent loose<br>stool; but no more than 30 mL<br>(6 tsp) in 24 hours | Inactive ingredients anhydrous citric<br>acid, carboxymethylcellulose sodium, D&C<br>yellow no. 10, FD&C blue no. 1, glycerin,                   |                        |
| children under<br>6 years<br>(up to 47 lbs)                                                           | ask a doctor                                                                        | microcrystalline cellulose, natural and artificial<br>mint flavor, propylene glycol, purified water,<br>simethicone, sodium benzoate, sucralose, |                        |
| Other information<br>■ each 30 mL (6 tsp) contains: sodium 15 mg<br>■ store between 20-25°C (68-77°F) |                                                                                     | titanium dioxide, xanthan gum<br><i>Questions or comments?</i><br>1-800-719-9260                                                                 |                        |
|                                                                                                       |                                                                                     |                                                                                                                                                  |                        |

| operamide hcl suspension                                  |                                 |             |                             |        |                   |  |
|-----------------------------------------------------------|---------------------------------|-------------|-----------------------------|--------|-------------------|--|
| Product Information                                       |                                 |             |                             |        |                   |  |
| Product T ype                                             | HUMAN OTC DRUG                  | Item Code ( | Source)                     | NDC:46 | DC:46122-111      |  |
| Route of Administration                                   | ORAL                            |             |                             |        |                   |  |
| Active Ingredient/Active Mo                               | piety                           |             |                             |        |                   |  |
| Ing                                                       | redient Name                    |             | Basis of Strength           |        | Strengtl          |  |
| L <b>OPERAMIDE HYDROCHLORIDE</b> (<br>UNII:6 X9 OC 3H4II) | UNII: 77TI35393C) (LOPERAMIDE - |             | LOPERAMIDE<br>HYDROCHLORIDE |        | 1 mg<br>in 7.5 mL |  |
| Inactive Ingredients                                      | Ingradiant Name                 |             |                             |        | Strongth          |  |
| ANHYDROUS CITRIC ACID (UNII: X                            | <b>Ingredient Name</b>          |             |                             |        | Strength          |  |
| CARBOXYMETHYLCELLULOSE S                                  |                                 |             |                             |        |                   |  |
| D&C YELLOW NO. 10 (UNII: 35SW5                            | , , ,                           |             |                             |        |                   |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3T                           |                                 |             |                             |        |                   |  |
| GLYCERIN (UNII: PDC6A3C0OX)                               |                                 |             |                             |        |                   |  |
| CELLULOSE, MICROCRYSTALLIN                                | IE (UNII: OP1R32D61U)           |             |                             |        |                   |  |
| PROPYLENE GLYCOL (UNII: 6DC9                              | Q167V3)                         |             |                             |        |                   |  |
| WATER (UNII: 059QF0KO0R)                                  |                                 |             |                             |        |                   |  |
| SODIUM BENZOATE (UNII: OJ245F)                            | E5EU)                           |             |                             |        |                   |  |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                              |                                 |             |                             |        |                   |  |
| TITANIUM DIO XIDE (UNII: 15FIX9V)                         | 210)                            |             |                             |        |                   |  |

| Color                     | GREEN (opaque, viscous)                               | Score                |                    |  |
|---------------------------|-------------------------------------------------------|----------------------|--------------------|--|
| Shape                     |                                                       | Size                 |                    |  |
| Flavor                    | MINT                                                  | Imprint Code         |                    |  |
| Contains                  |                                                       |                      |                    |  |
|                           |                                                       |                      |                    |  |
|                           |                                                       |                      |                    |  |
| Packaging                 |                                                       |                      |                    |  |
| # Item Code               | Package Description                                   | Marketing Start Date | Marketing End Date |  |
| <b>1</b> NDC:46122-111-26 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/17/2012           |                    |  |
|                           |                                                       |                      |                    |  |
|                           |                                                       |                      |                    |  |
| Marketing Inf             | ormation                                              |                      |                    |  |
| Marketing Categor         | y Application Number or Monograph Citation            | Marketing Start Date | Marketing End Date |  |
| ANDA                      | ANDA091292                                            | 02/17/2012           |                    |  |
|                           |                                                       |                      |                    |  |

# Labeler - Amerisource Bergen (007914906)

Revised: 7/2018

Amerisource Bergen