

GOOD SENSE LOPERAMIDE HYDROCHLORIDE- loperamide hcl suspension
L Perrigo Company

Perrigo 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 children 12 years and 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 years (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 years (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 6 years (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

Mint Flavor

Controls the Symptoms of Diarrhea

Loperamide Hydrochloride Oral Suspension

Anti-Diarrheal

Compare to active ingredient of Imodium® A-D

4 FL OZ (120 mL)

1 mg Loperamide Hydrochloride per 7.5 mL

Drug Facts

**Active ingredient Purpose
(in each 7.5 mL)**

Loperamide HCl
1 mg.....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

PEEL BACK HERE

NDC 0113-0645-26

GOODSENSE®

Mint Flavor

Controls the Symptoms of Diarrhea

Loperamide Hydrochloride Oral Suspension

Anti-Diarrheal

Compare to active ingredient of **Imodium® A-D**



4 FL OZ (120 mL)

1 mg Loperamide Hydrochloride per 7.5 mL

Do not use if printed plastic neckband is broken or missing

Gluten Free

Distributed By **Perrigo®**
Allegan, MI 49010



3 0113-0645-26 1

: 64526 C2 F2

Drug Facts (continued)

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 ►

Drug Facts (continued)

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 children 12 years and 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 years (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 ► |
|---------------------------------|---|

Drug Facts (continued)

| | |
|--------------------------------|---|
| children 6-8 years (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 6 years (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) ►

Drug Facts (continued)

■ 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

GOOD SENSE LOPERAMIDE HYDROCHLORIDE

loperamide hcl suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0113-0645 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II) | LOPERAMIDE HYDROCHLORIDE | 1 mg in 7.5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|----------|-------------------------|--------------|--|
| Color | GREEN (opaque, viscous) | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:0113-0645-26 | 120 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091292 | 01/31/2012 | |

Labeler - L Perrigo Company (006013346)

Revised: 6/2014

L Perrigo Company