

SUNMARK ANTI DIARRHEAL- loperamide hcl solution
A-S Medication Solutions

McKesson Anti-Diarrheal 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

Heart alert: Taking more than directed can cause serious heart problems or death

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
- use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.
- mL = milliliter

adults and children 12 years and over	30 mL after the first loose stool; 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours
children 9-11 years (60-95 lbs)	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours
children 6-8 years (48-59 lbs)	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 30 mL in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- **each 30 mL contains:** sodium 15 mg
- store between 20-25°C (68-77°F)

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

loperamide HCl



SUNMARK ANTI DIARRHEAL

loperamide hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4450(NDC:70677-0054)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4I)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4450-0	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	06/11/2018	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4450)

Revised: 8/2019

A-S Medication Solutions