SUNMARK ANTI DIARRHEAL- loperamide hcl solution Strategic Sourcing Services LLC

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
- a history of abnormal heart rhythm

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Loperamide may interact with certain prescription drugs.

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

	30 mL after the first loose stool; 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours
,	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

Package/Label Principal Display Panel

COMPARE TO IMODIUM® A-D ACTIVE INGREDIENT

See New Warning and Directions

Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL

anti-diarrheal

Anti-Diarrheal Oral Solution

CONTROLS THE SYMPTOMS OF DIARRHEA

GLUTEN FREE

MINT FLAVOR 4 FL OZ (120 mL)

Drug Facts

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

Peel open to read complete directions and warnings before purchase



NDC 70677-0054-1

See New Warning and Directions

Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL

anti-diarrh

Anti-Diarrheal Oral Solution

CONTROLS THE SYMPTOMS OF DIARRHEA

GLUTEN FREE

MINT FLAVOR

4 FL OZ (120 mL)

Do not use if printed plastic neckband is broken or missing.

MSKESSON

Another Quality Product Distributed By McKesson 6555 State Highway 161 Irving, TX 75039 Money Back Guarantee Please visit us at www.sunmarkbrand.com

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of lmodium® A-D.



: 64526 S1 F4

Drug Facts (continued)

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
- a history of abnormal heart rhythm

Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with certain prescription drugs.

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 getworse
- 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



Drug Facts (continued)

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

ı	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
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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

SUNMARK ANTI DIARRHEAL

loperamide hcl solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-0054

Route of Administration ORAL

Active Ingredient/Active Moiety

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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
AAEDODGI \	

ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)

 $\textbf{CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM} \, (\text{UNII: } K679\,\text{OBS}311)$

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

GLYCERIN (UNII: PDC6A3C0OX)

MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

SODIUM BENZOATE (UNII: OJ245FE5EU)

SUCRALOSE (UNII: 96K6UQ3ZD4)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

XANTHAN GUM (UNII: TTV12P4NEE)

DIMETHICO NE (UNII: 92RU3N3Y10)

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

Product Characteristics

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

Contains

Packaging

1	_	- ucing mg			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:70677-0054-1	120 mL in 1 BOTTLE: Type 0: Not a Combination Product	06/11/2018	

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

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 1/2020 Strategic Sourcing Services LLC