LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride liquid Western Family Foods Inc

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

Other information

- each 30 mL (6 tsp) contains: sodium 13 mg
- store between 20-25°C (68-77°F)
- do not use if printed plastic neckband is broken or missing
- 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 THE ACTIVE INGREDIENT OF IMODIUM® A-D LOPERAMIDE HYDROCHLORIDE ORAL SUSPENSION

Anti-Diarrheal

CONTROLS THE SYMPTOMS OF DIARRHEA MINT FLAVOR Gluten Free

1mg Loperamide Hydrochloride per 7.5 mL

Drug Facts

Active ingredient Purpose (in each 7.5 mL)

Loperamide HCI

1 mg.....Anti-diarrheal

Use controls symptoms of diarrhea, including Travelers' Diarrhea

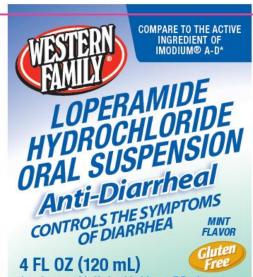
Warnings

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

d black stool

PEEL BACK HERE



1mg Loperamide Hydrochloride per 7.5 mL

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Portland, OR 97208
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Marca Registrada
www.westernfamily.com



*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Imodium® A-D.



: 64526 3W F1

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)

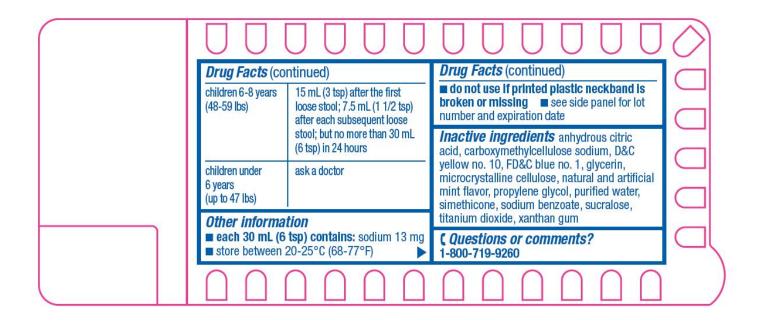
Directions ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea

■ 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



LOPERAMIDE HYDROCHLORIDE

loperamide hcl liquid

Product Information

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:55312-645

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthLOPERAMIDE HYDROCHLORIDE (LOPERAMIDE)LOPERAMIDE HYDROCHLORIDE1 mg in 7.5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID		
CARBO XYMETHYLCELLULO SE SO DIUM		
D&C YELLOW NO. 10		
FD&C BLUE NO. 1		
GLYCERIN		
CELLULOSE, MICRO CRYSTALLINE		
PROPYLENE GLYCOL		
WATER		
SO DIUM BENZO ATE		
SUCRALOSE		
TITANIUM DIO XIDE		
XANTHAN GUM		

Product Characteristics

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

	_	_
Pac	700	ina
Pac	KdY	1112

ı				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:55312-645-26	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	05/19/2012	

Labeler - Western Family Foods Inc (192166072)

Revised: 9/2013 Western Family Foods Inc