EQUALINE LOPERAMIDE HYDROCHLORIDE- loperamide hcl suspension Supervalu Inc

SuperValu Inc. 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	30 mL (6 tsp) after the first loose stool; 15 mL (3 tsp) after each
over	subsequent loose stool; but no more than 60 mL (12 tsp) in 24 hours
	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
	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?

1-877-932-7948

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

4 FL OZ (120mL)

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 black stool

PEEL BACK HERE

NDC 41163-645-26

compare to Imodium® A-D

EQUALINE®

loperamide hydrochloride oral suspension

anti-diarrheal

controls the of diarrhea

mint flavor

1 mg loperamide hydrochloride per 7.5 mL

4FLOZ (120mL)

Contact us at 1-877-932-7948, or www.supervalu-ourownbrands.com neckband is broken or missing. use if printed plastic not

*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Imodium®.

Distributed by SUPERVALU INC. Eden Prairie, MN 55344 USA ∞ **GLUTEN FREE** 9

HIIIIE• no varnish • no color

:64526 EL F3

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? 1-877-932-7948

EQUALINE LOPERAMIDE HYDROCHLORIDE

loperamide hcl suspension

Product	Infor	mation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-645

Route of Administration ORAL

Active Ingredient/Active Moiety

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) XANTHAN GUM (UNII: TTV12P4NEE)

ı	Active ingredient/Active molety			
l	Ingredient Name	Basis of Strength	Strength	
	LOPERAMIDE HYDRO CHLO RIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII: 6 X9 OC3H4II)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GLYCERIN (UNII: PDC6A3C0OX)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

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:41163-645-26	120 mL in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091292	02/06/2012		

Labeler - Supervalu Inc (006961411)

Revised: 3/2015 Supervalu Inc