## EQUALINE LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution Supervalu Inc

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SuperValu Inc. Loperamide Hydrochloride Oral Solution 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

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
(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
` '	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?

1-855-423-2630

#### **Principal Display Panel**

compare to Imodium® A-D active ingredient

loperamide hydrochloride oral solution, 1 mg per 7.5 mL (anti-diarrheal)

controls the symptoms of diarrhea

SEE NEW WARNING AND DIRECTIONS

mint flavor

anti-diarrheal oral solution

4 FL OZ (120mL)

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Peel open to read complete directions and warnings before purchase

NDC 41163-210-26

compare to Imodium®A-D active ingredient\*

## **EQUALINE®**

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controls the symptoms of diarrhea

SEE NEW WARNING AND DIRECTIONS

anti-diarrheal oral solution

4 FL OZ (120mL)

plastic neckband is broken or missing DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908 USA 855-423-2630 Do not use if printed

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

4 **GLUTEN FREE** 9 0

: 64526 EL F5

#### 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 historý of abnormal heart rhythm

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

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#### Stop use and ask a doctor if

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#### Directions

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

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#### Drug Facts (continued)

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■ 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?1-855-423-2630

### **EQUALINE LOPERAMIDE HYDROCHLORIDE**

loperamide hcl solution

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-210

Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE UNII:6X9OC3H4II) LOPERAMIDE HYDROCHLORIDE in 7.5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 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: 92RU3N3Y1O)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

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

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:41163-210-26	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091292	05/21/2018		

## Labeler - Supervalu Inc (006961411)

Revised: 1/2020 Supervalu Inc