EQUALINE LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution United Natural Foods, Inc. dba UNFI

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

adults and children	30 mL after the first loose stool; 15 mL after
12 years and over	each subsequent loose stool; but no more
	than 60 mL in 24 hours
children 9-11	15 mL after the first loose stool; 7.5 mL after
years	each subsequent loose stool; but no more
(60-95 lbs)	than 45 mL in 24 hours
children 6-8 years	15 mL after the first loose stool; 7.5 mL after
(48-59 lbs)	each subsequent loose stool; but no more
	than 30 mL in 24 hours
children 2-5 years	ask a doctor
(34 to 47 lbs)	
children under 2	do not use
years	
(up to 33 lbs)	
years	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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EQUALINE L		IIDE HYDROCHL	ORIDE			
Product Infor	mation					
Product Type		HUMAN OTC DRUG	Item Cod	de (Source)	NDC:41163-210	
			item cou		NDC.41105-210	
Route of Admin	istration	ORAL				
Active Ingred	ient/Active	Moiety				
	Ingred	lient Name		Basis of Stre	ength Stren	gth
LOPERAMIDE HYD UNII:6X9OC3H4II)	ERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - LOPERAMIDE				1 mg in 7.5 m	۱L
Inactive Ingre	dients					
9		Ingredient Name			Stren	ath
ANHYDROUS CITR		•	-		Streng	gen
		ODIUM, UNSPECIFIED FO	RM (UNII) K	(6790BS311)		
D&C YELLOW NO.				(075085511)		
FD&C BLUE NO. 1						
GLYCERIN (UNII: PI		,				
		E (UNII: OP1R32D61U)				
PROPYLENE GLYC	OL (UNII: 6DC9	Q167V3)				
WATER (UNII: 0590						
SODIUM BENZOAT	TE (UNII: 0J245I	E5EU)				
SUCRALOSE (UNII:						
TITANIUM DIOXID	E (UNII: 15FIX9\	(2JP)				
XANTHAN GUM (UI	NII: TTV12P4NEI	E)				
DIMETHICONE (UN	NII: 92RU3N3Y10))				
SILICON DIOXIDE	(UNII: ETJ7Z6XE	SU4)				
Product Chara	acteristics					
Color	GREEN (op	aque, viscous)		Score		
Shape				Size		
Flavor	MINT			Imprint Code		
Contains						
Packaging						
# Item Code	Pa	ckage Description	I	Marketing Start Date	Marketing E Date	nd
1 NDC:41163-210- 26	120 mL in 1 BO Product	DTTLE; Type 0: Not a Comb	ination 05	/21/2018		

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

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

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111

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