ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled Freds Inc

Drug Facts

Active Ingredient (in each capsule)

Loperamide HCI 2 mg

Purpose

Anti- diarrheal

Use

controls symptoms of diarrhea, including Traveler's 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
- in children under 12 years of age

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 gets 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 Certer right away.

Directions

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

- not for use in children under 12 years of age
- adults and children 12 years of age and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours

Other information

- store at 20°-25° C (68°-77° F). Protect from light.
- avoid excessive heat above 40°C (104°F).
- do not use if carton or blister unit is open or torn
- see side panel for lot number and expiration date

Inactive Ingredients

butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil and purified water.

Questions or comments?

call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Anti-Diarrheal

Loperamide HCl, 2mg

Controls the symptoms of diarrhea

Suitable For Adults And Children 12 Years And Over

SOFTGELS**

**each liquid-capsule contains 2 mg Loperamide HCl

Compare To The Active Ingredients in Imodium® A-D*

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL ROAD,

MEMPHIS, TN 38118

www.fredsinc.com

Product Label

This product is not manufactured or distributed by McNell Consumer & Specialty Pharmaceuticals, distributor of Imodium® A-D.

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Ask a doctor or pharmacist before use if you are

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- fever mucus in the stool

Ask a doctor before use if you have

- in children under 12 years of age
- if you have bloody or black stool

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SprinibW

Travelers' Diarrhea

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Loperamide HCI 2 mg.....Anti-diarrheal

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Purpose

professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center

If pregnant or breast-feeding, ask a health

Drug Facts (continued)

freds Pharmacy

Anti-Diarrheal

Loperamide HCI, 2 mg

NDC 55315-520-24



freds Pharmacy

Anti-Diarrheal

Loperamide HCI, 2 mg

A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT. I capton for complete warnings and product information. Fred's Pharmacy Anti-Diarrheal

ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:55315-520

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE UNII: 6 X9 OC3H4II)

LOPERAMIDE
HYDROCHLORIDE

2 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MO NO CAPRYLATE (UNII: TM2TZD4G4A)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	10 mm
Flavor		Imprint Code	P13
Contains			

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:55315-520-24	2 in 1 CARTON	07/08/2010				
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product					
Marketing Information							
Marketing Category		y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
NI	DA	NDA021855	07/08/2010				

Labeler - Freds Inc (005866116)

Revised: 8/2016 Freds Inc