LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet
Fred's Inc.

Drug Facts

ACTIVE INGREDIENT (IN EACH CAPLET)

Loperamide HCI USP, 2 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 HCI

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

- diarrhea lasts for more than 2 days
- symptoms get worse
- 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.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor

OTHER INFORMATION

- store between 20° – 25° C (68° – 77° F)
- see side panel for batch number and expiration date
- **TAMPER EVIDENT: THIS PRODUCT PROTECTED WITH SEALED BLISTER UNITS. DO NOT USE IF ANY ARE TORN OR BROKEN.**

INACTIVE INGREDIENTS

Anhydrous lactose, croscarmellose sodium, crospovidone, D&C yellow no.10, FD&C blue no.1, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

QUESTIONS?

Call **1800-406-7984**

PRINCIPAL DISPLAY PANEL

fred's®

Loperamide Hydrochloride Tablets USP, 2 mg

Anti-Diarrheal

Controls The Symptoms of Diarrhea

24 CAPLETS*

Each Caplet (*capsule-shaped tablet)

contains Loperamide HCl USP, 2 mg

Compare to Active Ingredient of Imodium® A-D†

DISTRIBUTED BY: fred's Inc.

5091235/R1111

fred's

Loperamide Hydrochloride Tablets USP, 2 mg

Anti-Diarrheal

fred's®

Shown at Actual Size

Loperamide Hydrochloride Tablets USP, 2 mg

Anti-Diarrheal

Controls The Symptoms of Diarrhea

24 CAPLETS*

Each caplet (*capsule-shaped tablet)

fred's LAB TESTED

Lab Tested for Quality, Fred Tested for Satisfaction

Compare To

oduct is not manufactured or distributed by McNeil-PPC, Inc., distributor of Imodium® A-D.

m® is a registered trademark of Johnson & Johnson.

Expiration Date:

Batch No.

NON VARNISH

5091235

5091235

Drug Facts

Active ingredient (in each caplet)	Purpose
Loperamide HCl USP, 2 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

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

■ diarrhea lasts for more than 2 days ■ symptoms get worse

■ 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.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor

Other information

■ store between 20° - 25° C (68° - 77° F)

■ see side panel for batch number and expiration date

■ **TAMPER EVIDENT: THIS PRODUCT PROTECTED WITH SEALED BLISTER UNITS. DO NOT USE IF ANY ARE TORN OR BROKEN.**

Inactive ingredients anhydrous lactose, croscarmellose sodium, crospovidone, D&C yellow no. 10, FD&C blue no. 1, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

Questions? call 1-800-406-7984

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-123
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TRISTEARIN (UNII: P6OCJ2551R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	green	**Score**	2 pieces
Shape	CAPSULE	**Size**	9mm
Flavor		**Imprint Code**	123
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:55315-123-06	6 in 1 BLISTER PACK		
2	NDC:55315-123-24	24 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074091	02/01/1993	

Labeler - Fred's Inc. (005866116)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(55315-123)

Revised: 1/2013 Fred's Inc.