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 $20^{\circ} 25^{\circ}$ C $(68^{\circ} 77^{\circ}$ 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

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

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

Other information

зак а doctor	children under 6 years (up to 47 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 6-8 years (48-59 lbs)
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2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours	adults and children 12 years and over
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Directions

keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away If pregnant or breast-feeding, ask a health professional before use.

- you get abdominal swelling or bulging. These may be signs of a serious condition.
 - symptoms get worse ■ diarrhea lasts for more than 2 days

Stop use and ask a doctor if

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Drug Facts (continued)

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Anti-diarmeal

esodin

operamide HCI USP, 2 mg

Active ingredient (in each caplet)

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Anti-Diarrheal

Controls The Symptoms of Diarrhea

24 CAPLETS*

Each caplet (*capsule-shaped tablet)



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LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

ı	Product	Information	

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:55315-123Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

 Ingredient Name
 Basis of Strength
 Strength

 LOPERAMIDE HYDRO CHLO RIDE (LOPERAMIDE)
 LOPERAMIDE HYDRO CHLO RIDE
 2 mg

Ingredient Name Strength ANHYDRO US LACTO SE CROSCARMELLO SE SODIUM CROSPO VIDO NE D&C YELLOW NO. 10 FD&C BLUE NO. 1 TRISTEARIN MAGNESIUM STEARATE POWDERED CELLULO SE STARCH, PREGELATINIZED CORN

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

P	ackaging			
#	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						
N	larketing Category	Application Number or Monogra	aph Citation	Marketing Start	Date	Marketing End Date
Al	NDA A	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.