LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet Family Dollar Services, 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
	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 lot 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

NDC 55319-554-53

FAMILY wellness TM

COMPARE TO THE ACTIVE INGREDIENT OF IMODIUM® A-D*

Anti-Diarrheal

Loperamide HCL Tablets USP, 2 mg

Controls the Symptoms of Diarrhea

12 CAPLETS[†]

Each caplet (†capsule-shaped tablet) contains Loperamide HCl USP, 2 mg

DISTRIBUTED BY: FAMILY DOLLAR SERVICES, INC.,

5085259/R0411

DO NOT USE IF ANY ARE TORN OR BROKEN.

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Other information

sak a doctor	children under 6 years (up to 47 lbs)
1 caplet after the first loose stool; 1/2 caplet after each anbeedneut loose stool; but no more than 2 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 3 caplets in 24 hours	children 9-11 years (60-95 lbs)
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

- tjud right dose on chart. If possible, use weight to dose; otherwise, use age.
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea Directions

5085259

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

When using this product $oldsymbol{m}$ when driving or operating machinery. $oldsymbol{m}$ it is the driving or operating machinery.

Ask a doctor or pharmacist before use if you are taking antibiotics

■ mucus in the stool ■ a history of liver disease Ask a doctor before use if you have

Dung Facts (continued)

Do not nae it you have bloody or black stool

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

USE controls symptoms of diarrhea, including Travelers' Diarrhea

Anti-diarmeal Purpose

Active ingredient (in each caplet)
Logical Company of the company

Drug Facts

wellness

COMPARE TO THE ACTIVE INGREDIENT OF IMODIUM* A-D'



Anti-Diarrhea

Loperamide HCI Tablets USP, 2 mg

Controls the Symptoms of Diarrhea

CAPLETS+

Each caplet (†capsule-shaped tablet) contain Loperamide HCI USP, 2 mg



"This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Imodium" A-D. Imodium"s is a registered trademark of Johnson. 8 Johnson.

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DISTRIBUTED BY: FAMILY DOLLAR SERVICES, INC.,

Family Dollar store for a refund (with receipt) or exchang Theilzifez 200f Joh

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-554

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	LOPERAMIDE HYDROCHLORIDE	2 mg

Inactive Ingredients

Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
CROSPO VIDO NE (UNII: 6840 1960 MK)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
TRISTEARIN (UNII: P6 O CJ2551R)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
PO WDERED CELLULOSE (UNII: SMD1X3XO9M)		
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)		

Product Characteristics

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)

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

Contains

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7	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-554-53	12 in 1 BLISTER PACK		

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ANDA	ANDA074091	02/01/1993

Labeler - Family Dollar Services, Inc. (024472631)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(55319-554)

Revised: 9/2012 Family Dollar Services, Inc.