

**LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet**  
**Shopko Stores Operating Co., LLC**

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**Drug Facts**

**ACTIVE INGREDIENT (IN EACH CAPLET)**

Loperamide HCl 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 HCl

**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.

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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

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**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**

**SHOPKO®**

**\*Compare to the active ingredient of Imodium® A-D**

**Anti-Diarrheal**

**Loperamide HCl Tablets USP, 2 mg**

**Anti-Diarrheal**

**Controls The Symptoms of Diarrhea**

**24 Caplets\***

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

**Manufactured by: Ohm Laboratories Inc.**

**5093693/R0212**

SHOPKO<sup>®</sup>  
**Anti-Diarrheal**  
 Loperamide HCl Tablets USP, 2 mg  
 Anti-Diarrheal  
 Controls The Symptoms of Diarrhea

SHOPKO<sup>®</sup>

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# Anti-Diarrheal

Loperamide HCl Tablets USP, 2 mg

Anti-Diarrheal

Controls The Symptoms of Diarrhea



**24 Caplets\***

**Keep the carton. Contains important information.**

\*This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Imodium<sup>®</sup> A-D. Imodium<sup>®</sup> is a registered trademark of Johnson & Johnson.

Batch No. \_\_\_\_\_ Expiration Date: \_\_\_\_\_

**NON VARNISH**

**Drug Facts**

**Active ingredient (in each caplet)**  
 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**  
 ■ drowsiness, dizziness or lightheadedness 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 bloating. 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.

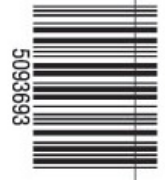
adults and children 17 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets 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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:370 12-123
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77T135393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (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

<b>Color</b>	green	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE	<b>Size</b>	9 mm
<b>Flavor</b>		<b>Imprint Code</b>	123
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:370 12-123-24	24 in 1 BLISTER PACK		

2 | NDC:37012-123-39 | 48 in 1 BOTTLE

## Marketing Information

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

**Labeler** - Shopko Stores Operating Co., LLC (023252638)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(37012-123)

Revised: 2/2013

Shopko Stores Operating Co., LLC