

**LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride capsule, liquid filled**

**Dr. Reddy's Laboratories Inc.**

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**Loperamide Hydrochloride Capsules USP, 2 mg, liquid filled**  
**Drug Facts**

**Active Ingredient (in each capsule)**

Loperamide Hydrochloride 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

**Heart alert:** Taking more than directed can cause serious heart problems or death

**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 stool
- a history of liver disease
- a history of abnormal heart rhythm

**Ask a doctor or pharmacist before use if you are**

taking a prescription drug. Loperamide may interact with certain prescription drugs.

**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 get 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 Center 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 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, FD&C Blue #1, gelatin, glycerol, glyceryl mono caprylo caprate, polyoxyl 40 hydrogenated castor oil, purified water,

printing ink white-edible oil – dewaxed bleached shellac resins, propylene glycol, sodium lauryl sulphate, titanium dioxide.

**Questions or comments?**

Questions or Comments? call toll-free weekdays 9 AM to 8 PM EST at **1-888-375-3784**

**Distributed by:**

Dr. Reddy's Laboratories Inc.,

Princeton, NJ 08540

Made in india

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**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.**

**PACKAGE LABEL. PRINCIPAL DISPLAY PANEL**

**\*\* COMPARE TO THE ACTIVE INGREDIENT IN IMODIUM<sup>®</sup> A-D**

**Loperamide Hydrochloride Capsules USP, 2 mg**

**Anti-Diarrheal**

**Controls the symptoms of diarrhea**

**Suitable for adults and children 12 years and over**

**24 Softgels\***

**\* each Liquid-filled capsule contains 2 mg Loperamide Hydrochloride, USP**





## LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-770
<b>Route of Administration</b>	ORAL		

### 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
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SHELLAC (UNII: 46N107B71O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	L2
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-770-24	2 in 1 CARTON	08/01/2023	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213070	10/22/2021	

**Labeler** - Dr. Reddy's Laboratories Inc. (802315887)

## Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	analysis(43598-770) , manufacture(43598-770) , pack(43598-770)

Revised: 6/2023

Dr. Reddy's Laboratories Inc.