LOPERAMIDE HYDROCHLORIDE - loperamide hydrochloride capsule, liquid filled
RITE AID CORPORATION

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

- 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?

Dial **1-877-244-9825 on weekdays from** 9 AM to 5 PM EST.

Manufactured by:

Strides Pharma Science Limited

Bengaluru-562106, India.

Distributed by:

Rite Aid

30 Hunter Lane, Camp Hill,

PA 17011.

Revised: 06/2022

†All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Imodium® A-D

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 ® A-D

NDC 11822-959-06

Loperamide Hydrochloride Capsules USP, 2 mg

Anti-Diarrheal

Suitable for adults and children 12 years and over

12 Softgels*

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

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-9590
Route of Administration	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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
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			
Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	L2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-9590-5	2 in 1 CARTON	06/30/2024	
1	NDC:11822-9590-3	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-9590-6	12 in 1 CARTON	06/30/2024	
2	NDC:11822-9590-3	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	06/30/2024	

Labeler - RITE AID CORPORATION (014578892)

Registrant - Strides Pharma Global Pte. Ltd. (659220961)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(11822-9590) , MANUFACTURE(11822-9590) , PACK(11822-9590)

Revised: 6/2022 RITE AID CORPORATION