

LOPERAMIDE HYDROCHLORIDE - loperamide hydrochloride capsule, liquid filled
Strides Pharma Inc

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?

go to **www.strides.com** or call Strides Pharma Inc. weekdays from 9 AM to 5 PM EST at **1-877-244-9825**

Manufactured by:

Strides Pharma Science Limited

Bengaluru-562106, India.

Distributed by:

Strides Pharma Inc.

East Brunswick, NJ 08816

Issued: 06/2020

†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 59556-959-06

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**

NO VARNISH ZONE

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Drug Facts (continued)

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40 hydrogenated castor oil, purified water,
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shellac resins, propylene glycol, sodium lauryl
sulphate, titanium dioxide.

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NO VARNISH ZONE
92 x 20 mm



OT To be

Manufactured by:
Strides Pharma Science Limited

Distributed by:
Strides Pharma Inc.



GRAIN DIRECTION

**LOPERAMIDE HYDROCHLORIDE**

loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-959
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
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

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:59556-959-06	1 in 1 CARTON	10/22/2021	
1	NDC:59556-959-03	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59556-959-05	2 in 1 CARTON	10/22/2021	

2	NDC:59556-959-03	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 - Strides Pharma Inc (078868278)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(59556-959) , MANUFACTURE(59556-959) , PACK(59556-959)

Revised: 10/2021

Strides Pharma Inc