

**LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride capsule**  
**Zydus Lifesciences Limited**

**Loperamide Hydrochloride Capsules, USP**

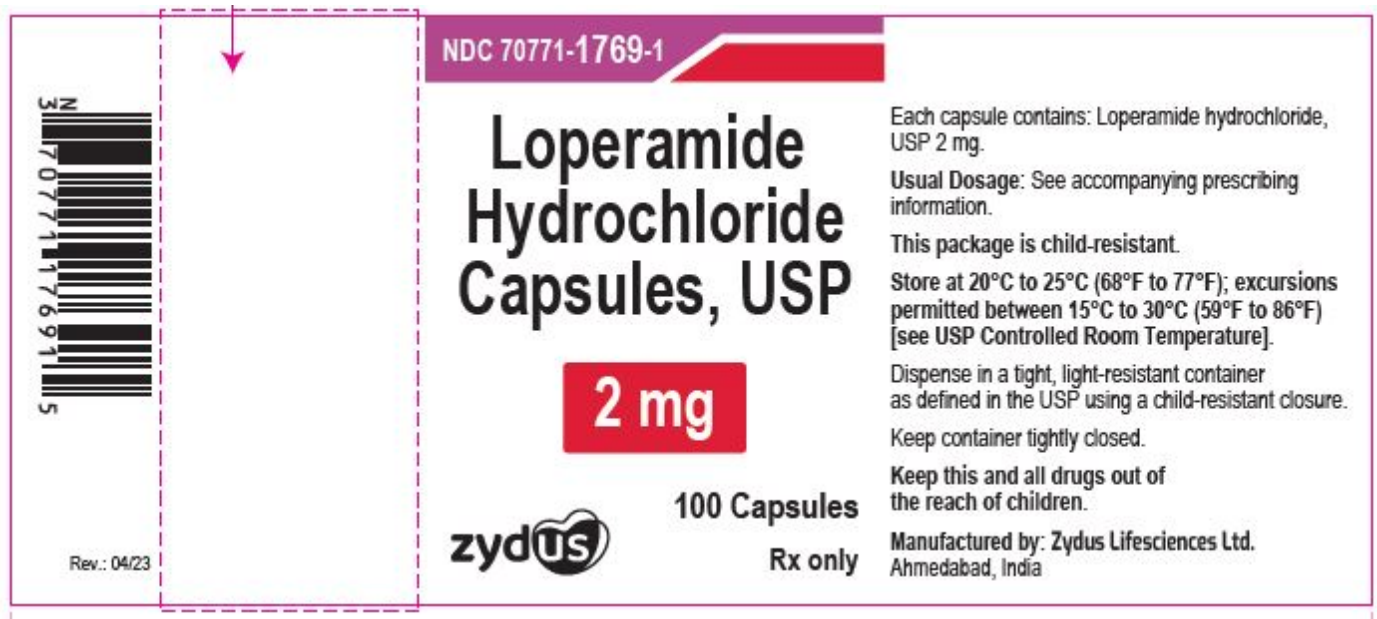
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Loperamide hydrochloride capsules USP, 2 mg

NDC 70771-1769-1

100 capsules

Rx only



**LOPERAMIDE HYDROCHLORIDE**

loperamide hydrochloride capsule

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1769
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE 101</b> (UNII: 7T9FYH5QMK)	
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	YELLOW (cream opaque cap) , YELLOW (cream opaque body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	1701
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1769-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2023	
2	NDC:70771-1769-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2023	
3	NDC:70771-1769-4	10 in 1 CARTON	06/25/2023	
3	NDC:70771-1769-2	10 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	ANDA217471	06/25/2023	

**Labeler** - Zydus Lifesciences Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 6/2023

Zydus Lifesciences Limited