

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride solution
Kesin Pharma Corporation

Loperamide HCl Oral Solution, USP

Active ingredient (in each 7.5 mL)

Loperamide HCl, USP 1 mg

Purpose

Anti-Diarrheal

Uses

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

Ask a doctor before use if you have

- fever
- mucus in the 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. (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.
- **shake well before using**

mL = milliliter

adults and children 12 years and over	30 mL after the first loose stool; 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours
children 9 years to 11 years (60 lbs to 95 lbs)	15 mL after first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours
children 6 years to 8 years (48 lbs to 59 lbs)	15 mL after first loose stool; 7.5 mL after each subsequent loose stool; but no more than 30 mL in 24 hours
children 2 years to 5 years (34 lbs to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- each 30 mL contains: **sodium 7 mg**
- store at 20°C to 25°C (68°F to 77°F)
- Loperamide HCl Oral Solution is a light green opaque, cool mint flavored solution supplied in the following:

NDC 81033-067-07: 7.5 mL unit-dose cup

NDC 81033-067-34: Carton containing 30 unit-dose cups of 7.5 mL each

NDC 81033-067-15: 15 mL unit-dose cup

NDC 81033-067-35: Carton containing 30 unit-dose cups of 15 mL each

Inactive ingredients

anhydrous citric acid, D&C Yellow No. 10, FD&C Blue No. 1, flavadew coolmint flavor, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, plain caramel powder, propylene glycol, purified water, simethicone emulsion, sodium benzoate, sucralose, titanium dioxide, xanthan gum

Questions or comments?

Call 1-616-218-2725

***This product is not manufactured or distributed by the owners of Imodium
® A-D.**

Distributed by:

Kesin Pharma

Oldsmar, FL 34677

PIS-067-V01

Rev. 05/2026



PRINCIPAL DISPLAY PANEL

NDC 81033-067-34

**Loperamide Hydrochloride Oral Solution, USP
1 mg per 7.5 mL**

Delivers 7.5 mL

30 x 7.5 mL Unit Dose Cups

NDC: 81033-067-34

**Loperamide Hydrochloride
Oral Solution USP
1 mg per 7.5 mL**

Delivers 7.5 mL

EXP: 00-000-0000 LOT: K0000000



(01)00381033067346(17)000000(10)K0000000

Packaged by and Distributed by
Kesin Pharma Corporation - Oldsmar, FL

FOR INSTITUTIONAL USE ONLY

**Loperamide Hydrochloride
Oral Solution, USP
1 mg per 7.5 mL**

30 x 7.5 mL Unit Dose Cups

EXP: 00-000-0000 LOT: K0000000

Store at 68°F to 77°F (20°C to 25°C)



See Insert
Internal Use Only R.01



K0000000

NDC 81033-067-35

**Loperamide Hydrochloride Oral Solution, USP
2 mg per 15 mL**

Delivers 15 mL

20 x 15 mL Unit Dose Cups

NDC: 81033-067-35

**Loperamide Hydrochloride
Oral Solution USP
2 mg per 15 mL**

Delivers 15 mL

EXP: 00-000-0000 LOT: K0000000



(01)00381033067353(17)000000(10)K0000000

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Kesin Pharma Corporation - Oldsmar, FL

FOR INSTITUTIONAL USE ONLY

**Loperamide Hydrochloride
Oral Solution, USP
2 mg per 15 mL**

30 x 15 mL Unit Dose Cups

EXP: 00-000-0000 LOT: K0000000

Store at 68°F to 77°F (20°C to 25°C)



See Insert
Internal Use Only R.01



K0000000

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81033-067(NDC:69452-405)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)		LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GLYCERIN (UNII: PDC6A3C0OX)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
CAMEL (UNII: T9D99G2B1R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0K00R)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	green (light green opaque)	Score		
Shape		Size		
Flavor	MINT (flavadow coolmint)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-067-34	30 in 1 CARTON	06/30/2026	
1	NDC:81033-067-07	7.5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-067-35	30 in 1 CARTON	06/30/2026	
2	NDC:81033-067-15	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA220100	11/13/2024		

Labeler - Kesin Pharma Corporation (117447816)

Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		117447816	label(81033-067) , pack(81033-067) , repack(81033-067)

Revised: 6/2026

Kesin Pharma Corporation