

**LOPERAMIDE HYDROCHLORIDE 2MG - loperamide hydrochloride tablets usp,
2mg tablet
MARKSANS PHARMA LIMITED**

Loperamide Hydrochloride Tablets USP, 2mg

ACTIVE INGREDIENT(S)

Active ingredient (in each tablet)

Loperamide HCl USP, 2 mg

PURPOSE

Purpose

Anti-diarrheal

USE(S)

Use controls symptoms of diarrhea, including Travelers' Diarrhea

WARNINGS

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

Do not use if you have bloody or black stool

ASK A DOCTOR BEFORE USE IF

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

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

When using this product tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

STOP USE AND ASK DOCTOR IF

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.

PREGNANCY/BREASTFEEDING

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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

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.

adults and children 12 years and over	2 tablets after the first loose stool; 1 tablet after each subsequent loose stool; but no more than 4 tablets in 24 hours
children 9-11 years (60-95 lbs)	1 tablet after the first loose stool; ½ tablet after each subsequent loose stool; but no more than 3 tablets in 24 hours
children 6-8 years (48-59 lbs)	1 tablet after the first loose stool; ½ tablet after each subsequent loose stool; but no more than 2 tablets in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

STORAGE

Other information

- store at 20°-25°C (68°-77°F)
- **do not use if carton or blister unit is open or torn**
- FDA approved dissolution test specifications differ from USP

INACTIVE INGREDIENTS

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Loperamide Hydrochloride (UNII: 77T135393C) (Loperamide - UNII:6X9OC3H4I1)	Loperamide Hydrochloride	2 mg

Inactive Ingredients

Ingredient Name	Strength
carnauba wax (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
croscarmellose sodium (UNII: M28OL1HH48)	
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)	
lactose monohydrate (UNII: EWQ57Q8I5X)	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polyethylene glycol (UNII: 3WJQ0SDW1A)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (white to off-white)	Score	2 pieces
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	L;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-001-83	4 in 1 CARTON	11/19/2025	
1		6 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	ANDA220153	11/19/2025	

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-001)

Revised: 11/2025

MARKSANS PHARMA LIMITED