ANTI DIARRHEAL- loperamide hydrochloride tablet, film coated
Preferred Pharmaceuticals Inc.

Major Pharmaceuticals Anti-Diarrheal Drug Facts

Active ingredient (in each caplet)

Loperamide HCl 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

Ask a doctor before use if you have

1. fever
2. mucus in the stool
3. a history of liver disease

Ask a doctor or pharmacist before use if you are

taking antibiotics

When using this product

tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

Stop use and ask a doctor if

1. symptoms get worse
2. diarrhea lasts for more than 2 days
3. 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.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets 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

Other information

- store at 20°-25°C (68°-77°F)
- see end panel for lot number and expiration date

Inactive ingredients

anhydrous lactose, carnauba wax, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

Questions or comments?

1-800-719-9260

Repackaged By: Preferred Pharmaceuticals Inc.

Principal Display Panel

See New Warning and Directions

Loperamide Hydrochloride Tablets, 2 mg

Anti-Diarrheal

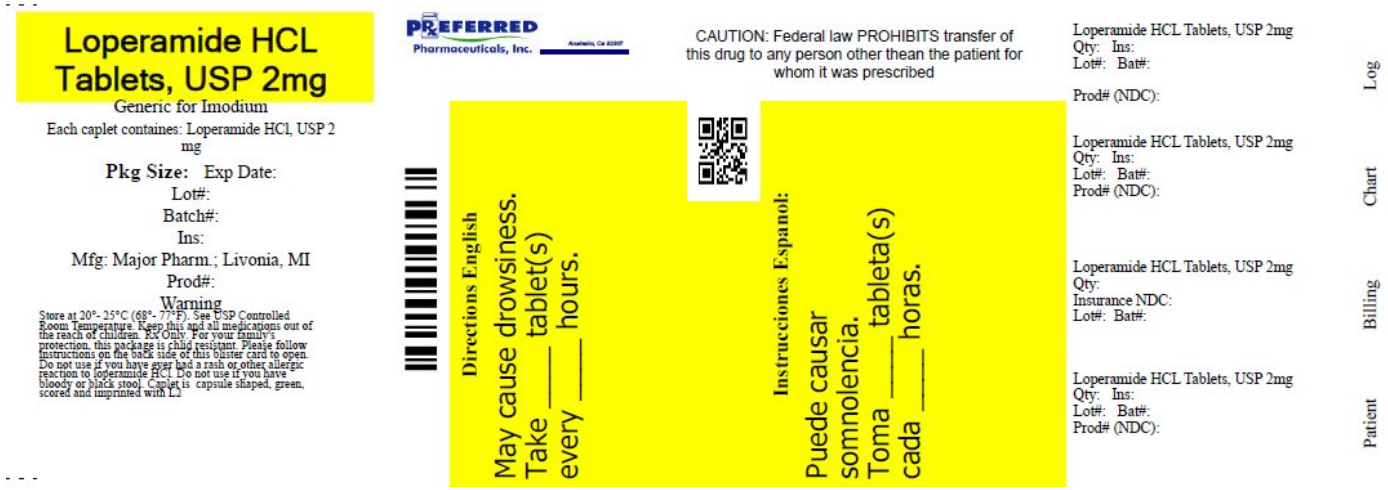
Anti-Diarrheal Controls the Symptoms of Diarrhea

Actual Size

*Capsule-Shaped Tablets

COMPARE TO active ingredient of IMODIUM® A-D

Repackaged By: Preferred Pharmaceuticals Inc.



ANTI DIARRHEAL

loperamide hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-8951(NDC:0904-7725)
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**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	GREEN	**Score**	2 pieces
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	L2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8951-1	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2015	
2	NDC:68788-8951-2	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2015	
3	NDC:68788-8951-3	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2015	
4	NDC:68788-8951-6	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075232	11/20/2015	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8951)

Revised: 7/2023 Preferred Pharmaceuticals Inc.