

ANTI DIARRHEAL- loperamide hydrochloride tablet, film coated
Redpharm Drug 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

- 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

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

Principal Display Panel

See New Warnings

Anti-Diarrheal

Loperamide Hydrochloride Tablets, 2 mg

Anti-Diarrheal Controls the Symptoms of Diarrhea

Actual Size

12 CAPLETS*

*Capsule-Shaped Tablets

COMPARE TO active ingredient of IMODIUM[®] A-D

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

MAJOR®

NDC 0904-7725-12

See New Warnings

Anti-Diarrheal

Loperamide Hydrochloride Tablets, 2 mg

Anti-Diarrheal
Controls the Symptoms of Diarrhea



Actual Size

12 CAPLETS*

*Capsule-Shaped Tablets

COMPARE TO active ingredient
of IMODIUM® A-D**

22453 5C C7

*This product is not manufactured or distributed by Johnson & Johnson Corp.

Drug Facts

Active ingredient (in each caplet)	Purpose
Loperamide HCl 2 mg.....	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

- fever ■ mucus in the stool
- a history of liver disease
- a history of an abnormal heart rhythm

Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with certain

Drug Facts (continued)

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 3 caplets in 24 hours

Distributed by: MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

M-05 REV. 07/19 Re-Order No. 700793

0



ANTI DIARRHEAL

loperamide hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1472(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: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

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:67296-1472-7	24 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075232	02/24/2003	

Labeler - Redpharm Drug Inc (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
Redpharm Drug Inc.		828374897	repack(67296-1472)

Revised: 2/2023

Redpharm Drug Inc