

# **ANTI DIARRHEAL- loperamide hydrochloride tablet, film coated**

## **Major Pharmaceuticals**

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### **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**

- 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.

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?**

**Principal Display Panel**

MAJOR®

compare to the active ingredient in Imodium® A-D

anti-diarrheal

loperamide hydrochloride tablets, 2 mg

anti-diarrheal

controls the symptoms of diarrhea

24 caplets\*

\*capsule-shaped tablets

actual size



22462 5C C8

**CODE AREA**

**OPEN OTHER END**

**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 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.

**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**

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**Other information**

■ store at 20° -25°C (68° -77°F)  
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**DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN**

Distributed by:  
**MAJOR PHARMACEUTICALS**  
 Indianapolis, IN 46268  
 (800) 616-2471  
 www.major-rugby.com

**CONVENIENT RECLOSING TAB**

**Drug Facts (continued)**

**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

\*\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Imodium® A-D.

Rev. 04/25 M-05 Re-order No. 006311



**ANTI DIARRHEAL**

loperamide hydrochloride tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7725
<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>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

## Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	L2
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7725-12	12 in 1 CARTON	02/24/2003	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-7725-24	24 in 1 CARTON	02/24/2003	
2		1 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	ANDA075232	02/24/2003	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 12/2025

Major Pharmaceuticals