ANTI DIARRHEAL- loperamide hydrochloride tablet, film coated
CVS Pharmacy

CVS Pharmacy, Inc. Anti-Diarrheal Drug Facts

Active ingredient (in each caplet)

Loperamide HCl 2 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.

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

Compare to the active ingredient in Imodium® A-D

Anti-Diarrheal

Loperamide Hydrochloride Tablets, 2 mg

Anti-Diarrheal

Controls the symptoms of diarrhea

SEE NEW WARNINGS

Actual Size

24 CAPLETS*

*Capsule-Shaped Tablets

CVSHealth

Loperamide Hydrochloride Tablets, 2 mg

Anti-Diarrheal

Controls the symptoms of diarrhea

CVSHealth

Compare to the active ingredient in Imodium® A-D†

Anti-Diarrheal

NDC 59779-700-62

Loperamide Hydrochloride Tablets, 2 mg

Anti-Diarrheal

Controls the symptoms of diarrhea

SEE NEW WARNINGS

Actual Size

24 CAPLETS*

*Capsule-Shaped Tablets

22462 17 C5

OPEN OTHER END

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

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

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).

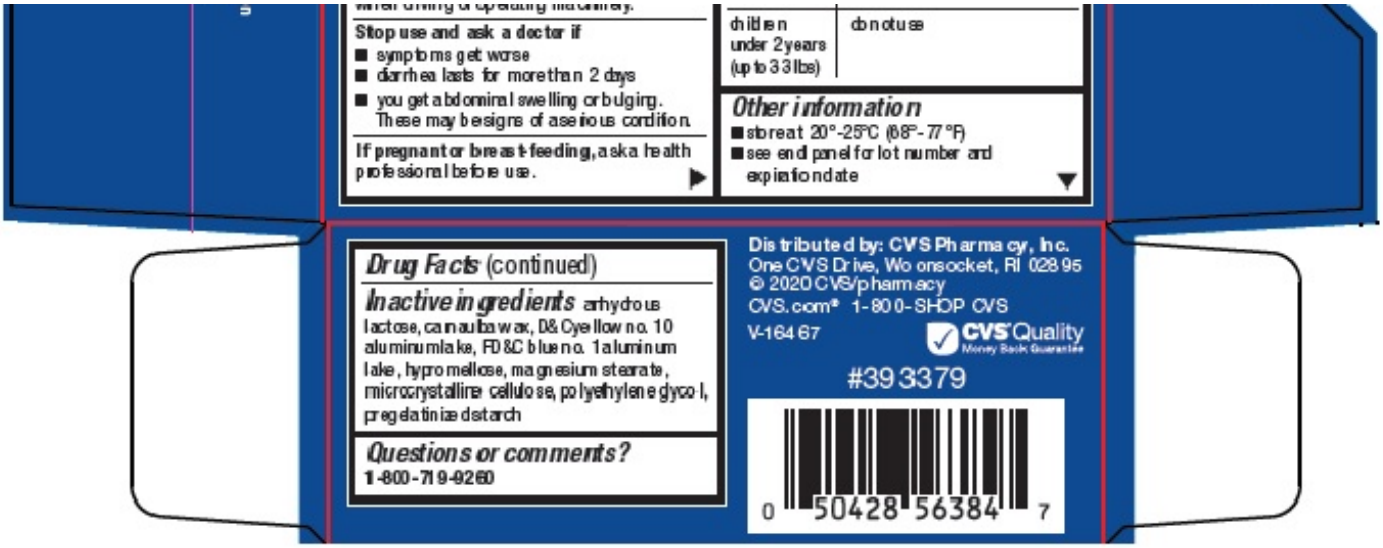
Directions

- 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 2 caplets in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

CONVENIENT RECLOSING TAB



ANTI DIARRHEAL

loperamide hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59779-700
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

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:59779-700-53	12 in 1 CARTON	05/12/2003	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59779-700-89	18 in 1 CARTON	08/21/2007	05/01/2013
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:59779-700-68	36 in 1 CARTON	03/06/2012	09/06/2013
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:59779-700-67	1 in 1 CARTON	02/24/2003	01/31/2022
4		48 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:59779-700-72	1 in 1 CARTON	02/21/2012	08/05/2016
5		60 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:59779-700-08	1 in 1 CARTON	02/21/2012	06/14/2014
6		108 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:59779-700-80	1 in 1 CARTON	05/24/2004	08/31/2021
7		96 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:59779-700-82	1 in 1 CARTON	06/18/2013	12/31/2021
8		200 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:59779-700-91	6 in 1 CARTON	04/07/2003	11/26/2008
9		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:59779-700-62	12 in 1 CARTON	11/08/2022	
10		2 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 - CVS Pharmacy (062312574)