# ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled CVS Pharmacy

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#### **Drug Facts**

# Active ingredient (in each capsule)

Loperamide HCI 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.

#### Do not use

- if you have bloody or black stool
- in children under 12 years of age (see *Other information*)

### Ask a doctor before use if you have

- fever
- mucus in the stool
- 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

- 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

- not for use in children under 12 years of age
- adults and children 12 years of age and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours

#### Other information

- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)
- see side panel for lot number and expiration date
- use the 1 mg soft gelatin capsule product for children 6 to under 12 years of age

#### **Inactive ingredients**

butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil and purified water.

#### Questions or comments?

Call toll free 1-800-447-1140

#### **Principal Display Panel**

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

#### ANTI-DIARRHEAL

CONTROLS THE SYMPTOMS OF DIARRHEA

LOPERAMIDE HCl SOFT GELATIN CAPSULES 2 mg

Suitable for adults and children 12 years and over

**SOFTGELS\*** 

\*Each liquid-filled capsule contains 2 mg loperamide hydrochloride

# THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

#### KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

### Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

www.cvs.com

Product of U.S.A.

†This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, owner of the registered trademark of Imodium® A-D.

#### **Product Label**

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**CONTROLS THE SYMPTOMS OF DIARRHEA** 

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**24** SOFTGELS'

\*Each liquid filled capsule contains 2 mg loperamide hydrochloride

LOPERAMIDE HCI SOFT GELATIN CAPSULES 2 mg **CONTROLS THE SYMPTOMS OF DIARRHEA** 

24 SOFTGELS

36 for the price of 24

NDC 59779-520-36

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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



CONTROLS THE SYMPTOMS OF DIARRHEA

LOPERAMIDE HCI SOFT GELATIN CAPSULES 2 mg Suitable for adults and children 12 years and over

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\*Each liquid filled capsule contains 2 mg loperamide hydrochloride



Actual Size

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

PLD-A FC001479

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Product of U.S.A.







LOT NO.:

Rev. #7/05

#948310

# CVS Anti-Diarrheal Softgel

# **ANTI-DIARRHEAL**

loperamide hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:59779-520
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength
ı	LOPERAMIDE HYDRO CHLO RIDE (LOPERAMIDE)	LOPERAMIDE HYDROCHLORIDE	2 mg

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDRO XYANISOLE		
FD&C BLUE NO. 1		
GELATIN		
GLYCERIN		
GLYCERYL CAPRYLATE		
POLYOXYL 40 HYDROGENATED CASTOR OIL		
WATER		

Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	10 mm	
Flavor		Imprint Code	P13	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:59779-520-24	2 in 1 CARTON			
1	12 in 1 BLISTER PACK			
2 NDC:59779-520-36	3 in 1 CARTON			
2	12 in 1 BLISTER PACK			
3 NDC:59779-520-48	4 in 1 CARTON			
3	12 in 1 BLISTER PACK			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA021855	07/08/2010		

Labeler - CVS Pharmacy (062312574)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 8/2013 CVS Pharmacy