

ANTI DIARRHEAL- loperamide hydrochloride tablet
Sam's West Inc

Simply Right 44-375

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 reactions to loperamide HCl.

Do not use

if you have bloody or black stool

Ask a doctor before use if you have

- high 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 (1-800-222-1222) right away.

Directions

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- find right dose on chat. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and older	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 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 under 6 years (up to 47 lbs)	ask a doctor

Other information

- do not use if carton or safety seal is broken or missing
- store between 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, D&C yellow # 10 aluminum lake, dicalcium phosphate dihydrate, FD&C blue #1 brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal Display Panel

NDC 68196-375-04

SIMPLY RIGHT™

Health Care

Loperamide Hydrochloride caplets, 2 mg

anti-diarrheal

Compare to Imodium A-D® active ingredient*

controls the symptoms of diarrhea

easy to swallow, small caplets

Each caplet (capsule-shaped tablets) contains 2 mg Loperamide Hydrochloride

350 caplets

*This product is not manufactured or distributed by McNeil consumer Healthcare, owner of the registered trademark Imodium A-D®.

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Distributed by:

SAM'S West, Inc.

Bentonville, AR 72716

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



Simply Right 44-375

ANTI DIARRHEAL

loperamide hcl tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:68196-375
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (LOPERAMIDE)	LOPERAMIDE HYDROCHLORIDE	2 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
D&C YELLOW NO. 10	
FD&C BLUE NO. 1	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	44;375
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-375-04	1 in 1 CARTON		
1		350 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076497	05/03/2005	

Labeler - Sam's West Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(68196-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(68196-375)

Revised: 10/2013

Sam's West Inc