

**ANTI-DIARRHEAL- loperamide hcl tablet**  
**SUPERVALU INC.**

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**Equaline 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 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**

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

***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 (34-47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

***Other information***

- store between 20°-25°C (68°-77°F)
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

***Questions or comments?***

**Call 1-877-932-7948**

***Principal Display Panel***

**EQUALINE®**

**compare to**

**Imodium® A-D**

active ingredient\*

NDC 41163-375-02

**anti-diarrheal**

loperamide HCl 2mg  
(anti-diarrheal)

*controls the  
symptoms of diarrhea*

**12 caplets**

actual size

**1.** To open, tear  
at perforations and  
remove a section.

**2.** Use □ to cut



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children under 2 years (up to 33 lbs)	do not use

**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.

**Warnings**  
 Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.  
 Allergy 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 ■ a 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 bloating. 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.

**Drug Facts (continued)**

44-375

## ANTI-DIARRHEAL

loperamide hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-375
<b>Route of Administration</b>	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
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

**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>	44;375
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-375-08	4 in 1 CARTON	05/03/2005	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41163-375-22	8 in 1 CARTON	05/03/2005	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41163-375-02	2 in 1 CARTON	05/03/2005	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:41163-375-44	3 in 1 CARTON	05/03/2005	
4		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:41163-375-46	1 in 1 CARTON	05/03/2005	
5		96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

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

**Labeler** - SUPERVALU INC. (006961411)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(41163-375)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(41163-375)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(41163-375)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(41163-375)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(41163-375)

Revised: 12/2019

SUPERVALU INC.