ANTI-DIARRHEAL- loperamide hcl tablet Geri-Care Pharmaceutical Corp

381

Active ingredient(in each caplet)

Loperamide HCI 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 HCI

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 present in your 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

- diarrhea lasts for more than 2 days
- symptoms get worse
- 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.

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

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 20°C-25°C (68°F-77°F)
- 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?

package Label



ANTI-DIARRHEAL

loperamide hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-381
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE UNII:6X9OC3H4II) LOPERAMIDE HYDROCHLORIDE 2 mg

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			

Product Characteristics			
Color	green (light green)	Score	2 pieces
Shape	CAPSULE	Size	7mm
Flavor		Imprint Code	44375
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-381- 25	4 in 1 CARTON	09/01/2020	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57896-381- 13	2 in 1 CARTON	03/01/2021	
2		6 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	ANDA076497	01/01/2006	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023 Geri-Care Pharmaceutical Corp