HANDY SOLUTIONS ANTI-DIARRHEAL- loperamide hydrochloride tablet
Navajo Manufacturing Company Inc.

Handy Solutions Anti-Diarrheal

Drug Facts

Active ingredient (in each caplet)

Loperamide Hydrochloride 2 mg

Purpose

Antidiarrheal

Uses

Controls the symptoms of diarrhea, including Traveler's 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 stools

Ask a doctor before use if you have

• a fever
• mucus in 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 more than 2 days
• you get abdominal swelling or bulging. These may be signs of a serious condition.

If you are pregnant or breast feeding,

ask a health professional before use.

Keep this and all drugs out of the reach of children.

In case of accidental overdose, contact a physician or Poison Control Center right away.

Directions

do not use more than directed
drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Adults and children (12 years and older):	Take 2 caplets after the first loose bowel movement followed by 1 caplet after each subsequent loose bowel movement but no more than 4 caplets in 24 hours.
Children under 12 years:	Do not give to children under 12 years of age.

Other information

- store between 68º - 77ºF (20º - 25ºC)
- tamper-evident sealed packets
- do not use any opened or torn packet

Inactive ingredients

anhydrous lactose, croscarmellose sodium, crospovidone, D&C yellow # 10, FD&C blue # 1, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

Questions or comments?

1-800-525-5097

Package Labeling:

HANDY SOLUTIONS ANTI-DIARRHEAL

loperamide hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-162(NDC:47682-200)
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	

Product Characteristics			
Color	green (green)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	10mm
Flavor		**Imprint Code**	123
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-162-01	1 in 1 CARTON	09/21/2016	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074091	09/21/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-162) , repack(67751-162)

Revised: 3/2023 Navajo Manufacturing Company Inc.