

DIFIXN- loperamide hydrochloride tablet
Goldman Pharmaceutical Group Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Difixn™

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Loperamide HCl 2 mg	Anti-diarrheal

Uses For the temporary relief of diarrhea

Warnings

- **Not for use** in the following breeds:
collie, sheltie, australian shepard, german shepard, old english sheep dog, long haired whippets
- **Do not use** with any other product containing Loperamide HCl
- **ask a veterinarian before use** if your dog has any chronic illness
- **stop use and ask veterinarian** if symptoms get worse or do not improve within 3 days
- **ask a veterinarian or pharmacist** if your dog is on any other medication
- **keep out of reach of children** in case of overdose contact poison control center
- **not for human use**

Directions

- give one dose every 8 hours as needed, not to exceed 3 doses in 24 hours
- 10 - 25 lbs take 1/2 caplet, 26 - 40 lbs take 1 caplet, 41 - 60 lbs take 2 caplets
- If diarrhea persists for more then 48 hours contact your veterinarian

Other information

- store at room temperature
20° - 25° (66° - 78° F)

Inactive Ingredients

cellulose, corn starch, D&C Yellow #10, dicalcium phosphate, FD&C Blue #1, magnesium stearate, silica gel

PRINCIPAL DISPLAY PANEL - 2 mg Caplet Bottle Label

pet
otc™
over the counter

Difixn™
Loperamide HCl 2 mg

ANTI-DIARRHEAL

10 to
60 lbs

20 CAPLETS

MADE IN THE USA

#1 VETERINARIAN
RECOMMENDED



Drug Facts	<p>Purpose Active ingredient Loperamide HCl 2 mg..... Anti-diarrheal</p> <p>Uses For the temporary relief of diarrhea</p> <p>Warnings <ul style="list-style-type: none"> Not for use in the following breeds: collie, sheltie, australian shepard, german shepherd, old english sheep dog, long haired whippets Do not use with any other product containing Loperamide HCl ask a veterinarian before use if your dog has any chronic illness stop use and ask veterinarian if symptoms get worse or do not improve within 3 days ask a veterinarian or pharmacist if your dog is on any other medication keep out of reach of children in case of overdose contact poison control center not for human use </p> <p>Directions <ul style="list-style-type: none"> give one dose every 8 hours as needed, not to exceed 3 doses in 24 hours 10 - 25 lbs take 1/2 caplet, 26 - 40 lbs take 1 caplet, 41 - 60 lbs take 2 caplets if diarrhea persists for more than 48 hours contact your veterinarian. </p> <p>Other information <ul style="list-style-type: none"> store at room temperature 20° - 25° C (66° - 78° F) </p> <p>Inactive Ingredients cellulose, corn starch, D&C Yellow #10, dicalcium phosphate, FD&C Blue #1, magnesium stearate, silica gel</p>
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DIFIXN

loperamide hydrochloride tablet

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:72087-013(NDC:66424-735)
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
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	GREEN (green)	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	44;375
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72087-013-20	20 in 1 BOTTLE		
2	NDC:72087-013-40	40 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/01/2019	

Labeler - Goldman Pharmaceutical Group Inc (080389804)

Registrant - Goldman Pharmaceutical Group, Inc. (080389804)

Establishment			
Name	Address	ID/FEI	Business Operations
Goldman Pharmaceutical Group, Inc.		080389804	RELABEL

Revised: 4/2019

Goldman Pharmaceutical Group Inc