ANTI DIARRHEAL ANTI GAS- loperamide hydrochloride, simethicone tablet H E B

HEB Anti-Diarrheal/Anti-Gas Drug Facts

Active ingredients (in each caplet)

Loperamide HCl 2 mg Simethicone 125 mg

Purposes

Anti-diarrheal

Anti-gas

Uses

relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

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
- if you have difficulty swallowing

Ask a doctor before use if you have

- 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.
- you have difficulty swallowing the caplet

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. (1-800-222-1222)

Directions

- · drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- take only on an empty stomach (1 hour before or 2 hours after a meal)
- take with a full (8 oz.) glass of water
- find right dose on chart below. 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; ½ 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; ½ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- each caplet contains: calcium 165 mg, sodium 3 mg
- store between 20°-25°C (68°-77°F). Protect from light.
- · do not use if printed blister unit is broken or torn

Inactive ingredients

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, maltodextrin, microcrystalline cellulose, natural and artificial flavor, propylene glycol, stearic acid

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Imodium[®] Multi-Symptom Relief active ingredients Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg Anti-Diarrheal/Anti-Gas Multi-Symptom Relief Caplet
Relieves symptoms of diarrhea plus
Cramps & Pressure - Bloating - Gas
actual size
24 CAPLETS*

*Capsule-Shaped Tablets



Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg

Anti-Diarrheal/Anti-Gas

Multi-Symptom Relief Caplet

Compare to Imodium® Multi-Symptom Relief
active Ingredients**

NDC 37808-714-62



Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg

Anti-Diarrheal/ Anti-Gas

Multi-Symptom Relief Caplet

Relieves symptoms of diarrhea plus

· Cramps & Pressure · Bloating · Gas

24 CAPLETS

Capsule-Shaped Tablets

Active ingredients (in each caplet) PurposesAnti-darrheal Loperamide ÄC12 m.g.. Simeth izone 1 25 m.g... ...Anti-cas

Uses relieves symptoms of diarrhea plus bloating, pressure an doramps, commonly referred to asgas

All lengy alent Do not useif you haveeverh ad a rash or other allergic reaction toloperamide HO He art a lent Taking more than directed cancause serious heart

Do not use

- if you have bloody or black stool
- if you have difficulty swallowing

Ask a do co rbefore use if you have

■ fever ■ mucus in the stool ■ a history of liver disease ■ a history of abnormal heartrhythm

Ask adoctororpharmacistbefore use if you are taking a p rescription drug. Loperam il ern ay interact with certain

p rescription drugs. When using this product tiredness, drowsinessor dizziness m ay occur. Be careful when driving or op grafing machin ery.

Stopuse and aska doctor if

- symptom sgetwose diarrhea lastsfor morethan 2 days youg et abdominal swelling orbulging. These maybe sign sof
- youh are difficulty swallowingthe caplet

Drug Facts (continued)

If pregnant or breast-feeding, ask aheath professional before use Keep out of leach of child len .incase of overdose, get medical heb or contact a Poison Control Center right away. (1-800 -222-12 22)

Directions

- m drink plan by of clear fluid sto help prevent dehydration caused by diarrhea
- ■take only on an empty stom ach(1 hourbefore or 2 hours after a meal)
- ■take with a full (8 oz) glassof water
- ■find right dose on chart below. If possible, use weight to dose; oth envise, usea ae.

adults and children 12 years and over	2caplets after the first bose shoot 1c apleta fler each subsequent boses tool; but no more than 4 caplets in 24 hours
chibbren 9-11 years (60 -95 lbs)	1 capet after the first lossest col; ½ capeta fler each subsequent losses tcol butno more than 3 caplets in 24 hours
chibbren 6-8 years (48 -59 lbs)	1 caplet after the first loss est col; ½ capleta fler each subsequent losses tool butno more than 2 caplets in 24 hours
chibbren 2-5 years (34 to 47 bs)	ask adodor
children under 2 years	donot use

Other information

mea ch cap let contains: cacium 1 65 mg , sodium 3 mg mstorebetwaen 20°-25°C (68°-77°F).Piotect from light. ■donot use if printed blister unit is broke nor torn

Drug Fac ts (continued)

Inactive ingredients accountamente assium, croscarmellose sodium, dibasic calcium phosphate. matrodextrin, microcrystalline cellulose, natural and artificial flavor, propylene glycol, stearb acid

Questions or comments? 1-900-719-9260





damandina, sauminina, 1 nos 115 or 25

GLUTEN FREE

™This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Imodium® Multi-Symptom Relief.



ANTI DIARRHEAL ANTI GAS

loperamide hydrochloride, simethicone tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-714
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	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg	

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	L0R1;2;125
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-714-53	12 in 1 CARTON	11/15/2018	
1		$1\ \text{in}\ 1\ \text{BLISTER}$ PACK; Type 0: Not a Combination Product		
2	NDC:37808-714-65	1 in 1 CARTON	11/19/2018	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:37808-714-62	24 in 1 CARTON	02/03/2020	
3		$1\ \text{in}\ 1\ \text{BLISTER}$ PACK; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA209837	11/15/2018		

Labeler - HEB (007924756)

Revised: 2/2020 HE B