TOPCARE ANTI DIARRHEAL ANTI GAS- loperamide hydrochloride, simethicone tablet Topco Associates LLC

Topco Associates LLC. 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?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO IMODIUM® MULTI-SYMPTOM RELIEF ACTIVE INGREDIENTS

Anti-Diarrheal

Anti-Gas

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

actual size



GLUTEN modium@Multi-Symptom Relief. This product is not manufactured or distributed by Johnson & Johns on Consumerinc, distributior of

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Drug Facts (continued)



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Anti-Diarrheal/Anti-Gas

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE TABLETS, 2 mg/125 mg ANTI-DIARRHEAL/ANTI-GAS



COMPARE TO IMODIUM® MULTI-SYMPTOM RELIEF **ACTIVE INGREDIENTS***

Anti-Diarrheal Anti-Gas

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













TOPCARE ANTI DIARRHEAL ANTI GAS

loperamide hydrochloride, simethicone tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-633

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE UNII:6X90C3H4II) DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) DIMETHICONE (125 mg

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
MICROCRYSTALLINE CELLULOSE (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:36800-633- 65	1 in 1 CARTON	10/09/2018	06/30/2021	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:36800-633- 53	12 in 1 CARTON	10/09/2018		

2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:36800-633- 62	24 in 1 CARTON	06/05/2020	
3		1 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	ANDA209837	10/09/2018	

Labeler - Topco Associates LLC (006935977)

Revised: 11/2021 Topco Associates LLC