

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

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**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 CAPLETST

†CAPSULE-SHAPED TABLETS

actual size



# TOPCARE ANTI DIARRHEAL ANTI GAS

loperamide hydrochloride, simethicone tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-633
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	L0R1;2;125
<b>Contains</b>			

## 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: 7/2024

Topco Associates LLC