

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride and simethicone tablet
Aurohealth LLC

Drug Facts

Active ingredients (in each caplet)

Loperamide HCl USP 2 mg
Simethicone USP 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 to 11 years (60 to 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 to 8 years (48 to 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 to 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 4 mg**
- store between 20° to 25°C (68° to 77°F). Protect from light.
- **do not use if carton is opened or if individual blister units are torn or opened**

Inactive ingredients

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate anhydrous, flavor, microcrystalline cellulose, stearic acid.

Questions or comments?

call 1-855-274-4122

(Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg/125mg (24 Caplets)
Blister Carton Label

NDC 58602-869-76

PrimaryHealth

**** COMPARE TO** Imodium®

Multi-Sympton Relief active ingredients

Loperamide HCl and Simethicone Tablets
2 mg/125 mg

Multi-Sympton Relief
Caplet

Loperamide HCl 2 mg - Antidiarrheal
Simethicone 125 mg - Anti-gas

Relieves symptoms of diarrhea *plus*

- **Cramps & Pressure**
- **Bloating**
- **Gas**

Actual Size

24 Caplets*

***capsule-shaped tablets**



Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58602-869 |
| 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 |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 125 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | |
| MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK) | |
| MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | WHITE (off-white) | Score | 2 pieces |
| Shape | CAPSULE | Size | 17mm |
| Flavor | VANILLA | Imprint Code | T;79 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:58602-869-76 | 4 in 1 CARTON | 02/24/2021 | |
| 1 | | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:58602-869-80 | 3 in 1 CARTON | 05/16/2021 | |
| 2 | | 6 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 | ANDA211059 | 02/24/2021 | |

Labeler - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED | | 650918514 | ANALYSIS(58602-869) , MANUFACTURE(58602-869) |

Revised: 12/2023

Aurohealth LLC