

ANTI-DIARRHEAL- loperamide hcl tablet
Better Living Brands, LLC

Signature Care 44-375

Active ingredient (in each caplet)

Loperamide HCl 2 mg

Purpose

Anti-diarrheal

Use

controls symptoms of diarrhea, including Travelers' Diarrhea

Warnings

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.

Do not use

if you have bloody or black stool.

Ask a doctor before use if you have

- a fever
- mucus in the stool
- a history of liver disease

Ask a doctor or pharmacist before use if you are

taking antibiotics.

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.

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 (1-800-222-1222) right away.

Directions

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- find right dose on chart. 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; 1/2 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; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours |
| children under 6 years (up to 47 lbs) | ask a doctor |

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store between 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, D&C yellow # 10 aluminum lake, dicalcium phosphate dihydrate, FD&C blue #1 brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal Display Panel

Signature[™]

care

Quality

Guaranteed

COMPARE TO

Imodium® A-D

active ingredient*

NDC 21130-375-08

Anti-Diarrheal

LOPERAMIDE HCl 2 mg

Anti-Diarrheal

Controls the symptoms
of diarrhea

Actual Size

24 CAPLETS

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributors of Imodium® A-D.

50844 REV0715L37508

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

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OUR PROMISE

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Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Warnings

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Ask a doctor or pharmacist before use if you are taking antibiotics.

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.

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Drug Facts (continued)

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B-1817-375-08-S
 REV0715L37508

24 CAPLETS



Actual Size

Controls the symptoms of diarrhea

Anti-Diarrheal
 LOPERAMIDE HCl 2 mg

Anti-Diarrheal

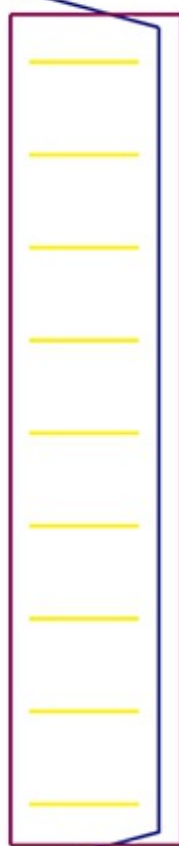
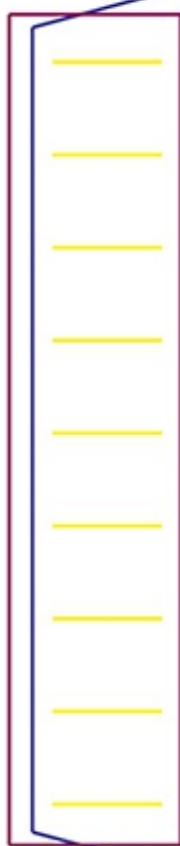
Quality Guaranteed

RD 16264

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DO NOT USE IF
 TORN OR IF BLISTER
 BROKEN OR SHOWS
 IF TAMPERING

Varnish
 exp. date

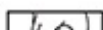


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OUR PROMISE
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 ON YOUR MONEY BACK.



1. To open, tear at perforations and remove a section.



2. The caplet is for



Signature Care 44-375

ANTI-DIARRHEAL

loperamide hcl tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21130-375 |
| 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 |
|--|----------|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | 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:21130-375-08 | 4 in 1 CARTON | 05/03/2005 | |

| | | | |
|---|------------------|--|------------|
| 1 | | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | |
| 2 | NDC:21130-375-22 | 1 in 1 CARTON | 05/03/2005 |
| 2 | | 48 in 1 BOTTLE; Type 0: Not a Combination Product | |
| 3 | NDC:21130-375-46 | 1 in 1 CARTON | 05/03/2005 |
| 3 | | 96 in 1 BOTTLE; Type 0: Not a Combination Product | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076497 | 05/03/2005 | |

Labeler - Better Living Brands, LLC (009137209)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | PACK(21130-375) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | MANUFACTURE(21130-375) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|----------------------------|
| LNK International, Inc. | | 967626305 | PACK(21130-375, 21130-375) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|----------------------------|
| LNK International, Inc. | | 832867837 | PACK(21130-375, 21130-375) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|----------------------------|
| LNK International, Inc. | | 868734088 | PACK(21130-375, 21130-375) |

Revised: 7/2017

Better Living Brands, LLC