

DATE 09/06/07

XXXXXXXX

Drug Facts

Active ingredients (in each caplet)

Loperamide HCl 2 mg
Simethicone 125 mg

Purposes

Anti-diarrheal
Anti-gas

Uses controls 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

Do not use if you have bloody or black stool

Ask a doctor before use if you have

■ fever ■ muscle 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 bloating
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 right away. (1-800-222-1222)

Directions

Drink plenty of clean fluids to help prevent dehydration caused by diarrhea

Take only on an empty stomach (1 hour before or 2 hours after a meal)

Find right dose on chart. If possible, use weight to dose; otherwise, use age

adults and children

12 years and over

children 9-11 years

children 6-8 years

children under 6 years

ask a doctor

Drug Facts (continued)

Other information

■ each caplet contains calcium 155 mg, sodium 4 mg

■ store between 20-25°C (68-77°F). Protect from light.

■ do not use if caplet is open or if printed foil seal under bottle cap is open or torn

■ see bottom panel for expiration date and lot number

Inactive ingredients

ascorbic acid, croscarmellose sodium, dibasic calcium phosphate, flavor, microcrystalline cellulose, stearic acid

Questions or comments?

call 1-877-899-3665 (English) or 1-888-466-6766 (Spanish)

The makers of Imodium® do not manufacture store brands.

Imodium®
loperamide HCl 2 mg/
simethicone 125 mg/
Advanced Imodium/Arth-Gas

ADVANCED
Controls the symptoms of
• diarrhea • bloating • pressure and cramps
30 Caplets Easy to Swallow

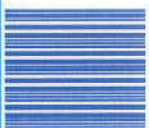
THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN
NDC 50580-XXX-XX

Easy to Open
Bottle

Imodium®
loperamide HCl 2 mg/
simethicone 125 mg/
Advanced Imodium/Arth-Gas

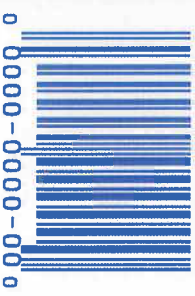
ADVANCED
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Imodium®
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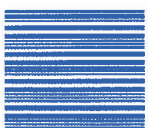
Controls the symptoms of
• diarrhea • bloating • pressure and cramps
PATENTED FORMULA



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McNEIL
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DIVISION OF MCNEIL-PPC, INC.
FORT WASHINGTON, PA 19034 USA
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U.S. Patent No. 6,103,260

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Labeling Format Information:

Font: Custom condensed medium, bold and bold italic

Drug Facts:

Header:

Subheader:

Body Text:

Drug Facts (continued):

8.25 pt

8 pt

6 pt

8 pt

Leading:

Bullets:

Barlines:

Headlines:

DESCRIPTION

FILE #

DATE

CTN IMODIUM Advanced Caplet 30 NCR

SMDA 3007441

9/06/07

Active ingredients
(in each caplet)

Loperamide HCl 2 mg.....Anti-diarrheal
Simethicone 125 mg.....Anti-gas
Uses: controls symptoms of diarrhea plus
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referred to as gas

Purposes

Anti-diarrheal
Anti-gas

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN
NDC 50580-XXX-XX

Imodium®

ADVANCED

Loperamide HCl, 2 mg/
Simethicone, 125 mg
Antidiarrheal/Anti-Gas
30 Caplets

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: • fever
• mucus in the stool • a history of liver disease

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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. 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 • 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 • each caplet contains: **calcium 165 mg, sodium 4 mg** • store between 20-25°C (68-77°F).

Protect from light • **do not use if printed foil seal under bottle cap is open or torn**

Questions or comments? call 1-877-895-3665 (English) or 1-888-466-8746 (Spanish)

Dist. by: MCNEIL-PPC, INC., FORT WASHINGTON, PA 19034 USA © MCN-PPC, Inc. '07 U.S. Patent No. 6,103,260

200% OF SIZE

Active ingredients
Loperamide HCl 2 mg.....Anti-diarrheal
Simethicone 125 mg.....Anti-gas
Uses: controls symptoms of diarrhea plus
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Anti-diarrheal
Anti-gas

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN
NDC 50580-XXX-XX

Imodium®

ADVANCED

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Simethicone, 125 mg
Antidiarrheal/Anti-Gas
30 Caplets

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Labeling Format Information:

Fonts: Custom condensed medium, bold and bold italic
Drug Facts: NA
Header: 4.5 pt
Subheader: 4.5 pt
Body Text: 4.5 pt
Drug Facts (continued): NA
Horizontal Scale: 80%
Average Kerning: 0

DESCRIPTION LBL IMODIUM Advanced Caplet 30 NCR

FILE # SNDA 3007441

VERSION E-5 (SNDA)

DATE 9/07/07