

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-140**

**APPROVED DRAFT LABELING**

COPY

NOV 16 1991

**Drug Facts (continued)**

**Other information**  
 Do not use if carton or blister unit is open or torn  
 Store between 20-25°C (68-77°F) protect from light  
 See side panel for expiration date and lot number.

**Inactive ingredients**  
 croscellose K, cellulose, dibasic calcium phosphate, fumed silica, hydroxypropyl methylcellulose, stearic acid.

Questions or comments? call 1-800-455-5132

**6 Capslets**

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas

**ANT-DIARRHEAL/ANTI-GAS**  
 Loperamide HCl/Simethicone

**ADVANCED Imodium.**

**Imodium ADVANCED**

LOT: 1000000000  
 EXP: 11/91

**6 Capslets**

**ADVANCED Imodium.**

**Drug Facts**

Active ingredient (in each capslet)	Purpose
Loperamide HCl 2 mg	Anti-diarrheal
Simethicone 125 mg	Anti-gas

USES: Controls symptoms of diarrhea, gas, bloating, pressure, and cramps commonly referred to as gas.

**Warnings**  
 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 stools.  
 Ask a doctor before use if you have had a heart attack or are on the verge of a heart attack, if you have a history of low blood pressure, if you are pregnant or breastfeeding, or if you are taking antacids.  
 Stop use and call a doctor if symptoms get worse, if diarrhea lasts for more than 2 days, if you get or have a fever, or if you have a severe stomach ache.  
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**  
 To drink plenty of clear fluids to help prevent dehydration caused by diarrhea.  
 If you feel right down on your feet, it is possible you might be dehydrated; otherwise, use age:

Adults and children 12 years and over	2 capsules after the first loose stool; 1 capsule after each subsequent loose stool; but no more than 2 capsules in 24 hours
Children 6-11 years 100-155 lbs	1 capsule after the first loose stool; 1/2 capsule after each subsequent loose stool; but no more than 2 capsules in 24 hours
Children 6-11 years 45-99 lbs	1 capsule after the first loose stool; 1/2 capsule after each subsequent loose stool; but no more than 2 capsules in 24 hours
Children under 6 years (up to 47 lbs)	ask a doctor

**Labeling Format Information:**

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	8.5 pt	Leading:	6.5 pt
Header:	8 pt	Bullets:	5 pt
Subheader:	6 pt	Barlines:	2.5 pt
Body Text:	6 pt	Hairlines:	0.5 pt
Drug Facts (continued):	8 pt		

Horizontal Scale: 85-95%      Average Kerning: -20

5.b NOV 16 2007

**Imodium**  
ADVANCED  
Loperamide HCl  
ANTIDIARRHEAL/ANT-DIARR

Control the symptoms of diarrhea and bloating, prevent, and relieve associated abdominal gas

2 Caplets

**Drug Facts**  
**Active Ingredient Purpose (in each caplet)**  
Loperamide HCl 1 mg Anti-diarrheal  
Dicyclanole 5.6 mg Ant-cholin

**Use** Controls symptoms of diarrhea plus bloating, prevents, and relieves associated abdominal gas

**Warnings**  
Already sick? 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 or think it possible to be sick or a history of liver disease  
Ask a doctor or pharmacist before use if you are taking antibiotics

**Drug Facts (continued)**

Stop use and ask a doctor if  
 • symptoms get worse  
 • diarrhea lasts for more than 2 days

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.

**Directions**  
 Drink plenty of clear fluids to help prevent dehydration caused by diarrhea. A first 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 6-11 years (60-66 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 4-5 years (46-55 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 4 years (up to 47 lbs)	ask a doctor

**Other information**  
 Do not use if sounds is open or torn  
 Store between 68°F-77°F  
 protect from light

**Inactive ingredients** acetaminophen K, cellulose, dibasic calcium phosphate, ferrous, sodium starch glycolate, stearic acid

**Questions or comments?**  
 call 1-800-942-5337

United Consumer Healthcare  
 DIVISION OF BAXTER PPC, INC.  
 1007 WASHINGTON, PA 15088-1511 800-942-5337, ext. 10  
 U.S. Patent Nos. 5,724,584, 5,712,585 and 5,742,585

**Labeling Format Information:**

Fonts: Helvetica regular, bold and bold italic.	
Drug Facts: 8.5 pt	Leading: 6.5 pt
Header: 8 pt	Bullets: 5 pt
Subheader: 6 pt	Barlines: 2.5 pt
Body Text: 6 pt	Hairlines: 0.5 pt
Drug Facts (continued): 8 pt	
Horizontal Scale: 85-87%	Average Kerning: -5

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each caplet)</b> Loperamide HCl 2 mg Simethicone 125 mg Anti-diarrheal Anti-gas</p> <p><b>Purpose</b></p> <p>Use controls symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas</p> <p><b>Warnings</b></p> <p>Allegry alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl</p> <p>Do not use if you have bloody or black stool</p> <p>Ask a doctor before use if you have a fever, mucus in the stool, or a history of liver disease</p> <p>Ask a doctor or pharmacist before use if you are taking antibiotics</p> <p>Stop use and ask a doctor if symptoms get worse or diarrhea lasts for more than 2 days</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <p>Drink plenty of clear fluids to help prevent dehydration caused by diarrhea</p> <p>Find right dose on chart. If possible, use weight to dose; otherwise, use age</p>	<p>adults and children 2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours</p> <p>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</p> <p>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</p> <p>ask a doctor children under 6 years (up to 47 lbs)</p>
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**XXXXXX**

# Imodium<sup>®</sup> ADVANCED

Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas

PATENTED FORMULA

**12 Caplets**

NDC 50580-922-72

# Imodium<sup>®</sup> ADVANCED

Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas

**NEW Easy to Swallow**

**12 Caplets**

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

**Other information**

- do not use if carton or blister unit is open or torn
- store between 20-25°C (68-77°F) protect from light
- see side panel for expiration date and lot number

**Inactive ingredients**

ascorbic acid, calcium phosphate, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

**Questions or comments?** call 1-800-962-5357

**EASY TO OPEN PACKAGE**

1. Tear off a bubble.  
2. Push Caplet through slot. Do Not Touch Caplet.

0 0000-00000-00

**McNEIL**  
McNeil Consumer Healthcare  
DIVISION OF MCNEIL-PPC, INC.  
PO BOX 1000  
FORT WASHINGTON, PA 19004 USA  
© 1997 McNeil-PPC, Inc. All rights reserved. NDC 50580-922-72

**Imodium<sup>®</sup> ADVANCED**  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

LOT: \_\_\_\_\_ EXP: \_\_\_\_\_

**Labeling Format Information:**

Fonts:	Helvetica regular, bold and bold italic.
Drug Facts:	8.5 pt
Header:	8 pt
Subheader:	6 pt
Body Text:	6 pt
Drug Facts (continued):	8 pt
Leading:	6.5 pt
Bullets:	5 pt
Barlines:	2.5 pt
Hairlines:	0.5 pt

Horizontal Scale: 85-95%      Average Kerning: -15

<p><b>Directions</b></p> <p>■ 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</p> <p>adults and children          2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours</p> <p>children 9-11 years          1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours</p> <p>children 6-8 years          1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours</p> <p>children under 6 years          ask a doctor          (up to 47 lbs)</p>	<p><b>Warnings</b></p> <p>Do not use if you have bloody or black stool</p> <p>Ask a doctor before use if you have ■ fever ■ mucus in the stool ■ a history of liver disease</p> <p>Ask a doctor or pharmacist before use if you are taking antibiotics ■ diarrhea lasts for more than 2 days</p> <p>Stop use and ask a doctor if ■ symptoms get worse ■ diarrhea lasts for more than 2 days</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each caplet)</b></p> <p>Loperamide HCl 2 mg          Simethicone 125 mg</p> <p><b>Purpose</b></p> <p>Anti-diarrheal          Anti-gas</p> <p><b>Use</b> controls symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas</p>	<p><b>Warnings</b></p> <p>Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl</p>

**Imodium** **ADVANCED**  
 Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas

PATENTED FORMULA

**18 Caplets**

NDC 50580-922-18

**Imodium** **ADVANCED**  
 Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas

**NEW Easy to Swallow**

**18 Caplets**

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

**Questions or comments?** call 1-800-952-5357

**Other information**

do not use if carton or blister unit is open or torn

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

■ see side panel for expiration date and lot number

**Inactive ingredients** acetylsalicylic acid, dicalcium phosphate, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

**Questions or comments?** call 1-800-952-5357

**McNEIL-PPC**  
 McNeil Consumer Healthcare  
 1000 North 17th Street  
 Fort Worth, TX 76101 USA  
 800-952-5357  
 U.S. Patent Nos. 5,248,305 and 5,417,264

**Imodium** **ADVANCED**  
 Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

**EASY TO OPEN PACKAGE**

1. Tear Off a Section
2. Fold Corner Inward and Peel Back Caplet

**0 00000-00000-00 0**

**Labeling Format Information:**

Fonts: Helvetica regular, bold and bold italic.	
Drug Facts: 8.5 pt	Leading: 6.5 pt
Header: 8 pt	Bullets: 5 pt
Subheader: 6 pt	Barlines: 2.5 pt
Body Text: 6 pt	Hairlines: 0.5 pt
Drug Facts (continued): 8 pt	

Horizontal Scale: 95%      Average Kerning: 0

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# Imodium. ADVANCED

Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

PATENTED FORMULA

30 Caplets

Each caplet contains  
2 mg loperamide HCl  
and 125 mg simethicone

XXXXXXX

### Drug Facts (continued)

#### Other information

- do not use if carton is open or if printed foil seal under bottle cap is open or torn
- store between 20-25°C (68-77°F)
- protect from light
- see side panel for expiration date and lot number

**Inactive ingredients** acesulfame K, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

**Questions or comments?**  
call 1-800-962-5357

# Imodium.

ADVANCED  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

PATENTED FORMULA

Each caplet contains  
2 mg loperamide HCl  
and 125 mg simethicone

# Imodium.

ADVANCED  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

**NEW**  
Easy to  
Swallow

30 Caplets

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN



0 0000-0000-00 0

EXP.

# Imodium.

ADVANCED  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

PATENTED FORMULA

McNeil

McNeil Consumer Healthcare  
DIVISION OF MCNEIL-PPC, INC.,  
FORT WASHINGTON, PA 19034 USA  
CMCN-PPC, Inc. '00

U.S. Patent Nos. 5,248,505 and 5,612,054

### Drug Facts

Active ingredient (in each caplet)	Purpose
Loperamide HCl 2 mg	Anti-diarrheal
Simethicone 125 mg	Anti-gas

#### Use

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  mucus in the stool  a history of liver disease

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

Stop use and ask a doctor if  
 symptoms get worse  diarrhea lasts for more than 2 days

If pregnant or breast-feeding, ask a health professional before use  
Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center 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

#### Labeling Format Information:

Fonts: Helvetica regular, bold and bold italic.

Drug Facts: 8.5 pt Leading: 6.5 pt

Header: 8 pt Bullets: 5 pt

Subheader: 6 pt Barlines: 2.5 pt

Body Text: 6 pt Hardlines: 0.5 pt

Horizontal Scale: 82-90% Average Kerning: -20

NDC 50580-922-30

**Imodium<sup>®</sup> ADVANCED**  
Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

**30 Caplets**

**FPO**

**Active Ingredient (in each caplet)**  
Loperamide HCl 2 mg  
Simethicone 125 mg  
Use • 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 • mucus in the stool • a history of liver disease. Ask a doctor or pharmacist before use if you are taking antibiotics. Stop use and ask a doctor if • symptoms get worse • diarrhea lasts for more than 2 days. 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.  
**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 •** do not use if printed foil seal under bottle cap is open or torn • store between 20-25°C (68-77°F) • protect from light  
**Questions or comments?** call 1-800-962-5357 MCNEIL-PPC, INC. FORT WASHINGTON, PA 19034 USA © MCNEIL-PPC, Inc. '00 [XXXXXXXXXX]

Purpose:  
Anti-diarrheal  
Anti-gas

LOT EXP.

150% OF SIZE

**Labeling Formal Information: (modified)**

Font: Helvetica regular, bold and bold italic	
Drug Facts:	0 pt
Header:	4.5 pt
Subheader:	4.5 pt
Body Text:	4.5 pt
Drug Facts (continued):	0 pt
Horizontal Scale:	77-79%
Average Kerning:	-30

NDC 50580-922-30

**Imodium<sup>®</sup> ADVANCED**  
Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

**30 Caplets**

**FPO**

**Active Ingredient (in each caplet)**  
Loperamide HCl 2 mg  
Simethicone 125 mg  
Use • 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 • mucus in the stool • a history of liver disease. Ask a doctor or pharmacist before use if you are taking antibiotics. Stop use and ask a doctor if • symptoms get worse • diarrhea lasts for more than 2 days. 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.  
**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 •** do not use if printed foil seal under bottle cap is open or torn • store between 20-25°C (68-77°F) • protect from light  
**Questions or comments?** call 1-800-962-5357 MCNEIL-PPC, INC. FORT WASHINGTON, PA 19034 USA © MCNEIL-PPC, Inc. '00 [XXXXXXXXXX]

Purpose:  
Anti-diarrheal  
Anti-gas

LOT EXP.

00000000



FPO

# Imodium. ADVANCED

Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

PATENTED FORMULA

42 Caplets

Each caplet contains  
2 mg loperamide HCl  
and 125 mg simethicone

XXXXXXX

### Drug Facts (continued)

#### Other information

- do not use if carton is open or if printed foil seal under bottle cap is open or torn
- store between 20-25°C (68-77°F)
- protect from light
- see side panel for expiration date and lot number

#### Inactive ingredients

acesulfame K, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

#### Questions or comments?

call 1-800-962-5357

# Imodium.

ADVANCED  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

PATENTED FORMULA

Each caplet contains  
2 mg loperamide HCl  
and 125 mg simethicone

Now  
in a  
Bottle!



# Imodium.

ADVANCED  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

**NEW**  
Easy to  
Swallow

42 Caplets

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

NDC-50580-922-42

# Imodium.

ADVANCED  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of  
diarrhea  
plus bloating,  
pressure,  
and cramps  
commonly referred  
to as gas

PATENTED FORMULA

McNeil Consumer Healthcare  
DIVISION OF MCNEIL-PPC, INC.,  
FORT WASHINGTON, PA 19034 USA  
©MCN-PPC, Inc. '00  
U.S. Patent Nos. 5,248,505 and 5,612,054

### Drug Facts

Active ingredient (in each caplet)	Purpose
Loperamide HCl 2 mg	Anti-diarrhea
Simethicone 125 mg	Anti-gas

#### Use

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
- mucus in the stool
- a history of liver disease

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

Stop use and ask a doctor if

- symptoms get worse
- diarrhea lasts for more than 2 days

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.

#### 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
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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

#### Labeling Format Information:

Fonts: Helvetica regular, bold and bold italic.  
Drug Facts: 8.5 pt  
Header: 8 pt  
Subheader: 6 pt  
Body Text: 6 pt  
Drug Facts (continued): 8 pt  
Leading: 5 pt  
Bullets: 5 pt  
Barlines: 2.5 pt  
Hairlines: 0.5 pt

Horizontal Scale: 97-100%

Average Kerning: 0



FPO

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FPO

0 0000-0000-00 0

EXP.



NDC 50580-822-42

# Imodium<sup>®</sup> ADVANCED

**Loperamide HCl/Simethicone**  
**ANTI-DIARRHEAL/ANTI-GAS**  
Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas

**42 Caplets**

**Active ingredient (in each caplet)**  
Loperamide HCl 2 mg  
Simethicone 125 mg

**Use** • 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 • mucus in the stool • a history of liver disease. Ask a doctor or pharmacist before use if you are taking antibiotics. Stop use and ask a doctor if • symptoms get worse • diarrhea lasts for more than 2 days.  
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.

**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

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children under 6 years (up to 47 lbs)	ask a doctor

**Other information** • do not use if printed foil seal under bottle cap is open or torn • store between 20-25°C (68-77°F) • protect from light  
Questions or comments? call 1-800-962-5357

MCNEIL-PPC, INC. FORT WASHINGTON, PA 19034 USA © MCN-PPC, Inc. '00

XXXXXXXXXX

LOT EXP.

150% OF SIZE

**Labeling Format Information: (modified)**

Font: Helvetica regular, bold and bold italic.	
Drug Facts:	0 pt
Header:	4.5 pt
Subheader:	4.5 pt
Body Text:	4.5 pt
Drug Facts (continued):	0 pt
Leading:	4.75 pt
Bullets:	5 pt
Barlines:	0 pt
Hairlines:	0.25 pt

Horizontal Scale: 87-90%      Average Kerning: -20

NDC 50580-822-42

# Imodium<sup>®</sup> ADVANCED

**Loperamide HCl/Simethicone**  
**ANTI-DIARRHEAL/ANTI-GAS**  
Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas

**42 Caplets**

**Active ingredient (in each caplet)**  
Loperamide HCl 2 mg  
Simethicone 125 mg

**Use** • 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 • mucus in the stool • a history of liver disease. Ask a doctor or pharmacist before use if you are taking antibiotics. Stop use and ask a doctor if • symptoms get worse • diarrhea lasts for more than 2 days.  
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.

**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** • do not use if printed foil seal under bottle cap is open or torn • store between 20-25°C (68-77°F) • protect from light  
Questions or comments? call 1-800-962-5357

MCNEIL-PPC, INC. FORT WASHINGTON, PA 19034 USA © MCN-PPC, Inc. '00

XXXXXXXXXX

LOT EXP.


**OTC  
ANTIDIARRHEAL/ANTI-GAS**

# Imodium.

## ADVANCED

Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas



**Easy to Swallow**

**2 Caplets**

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

**SAMPLE • NOT TO BE SOLD**

**Drug Facts**

Active Ingredient (in each caplet)	Purpose
Loperamide HCl 2 mg.....	Anti-diarrheal
Simethicone 125 mg.....	Anti-gas

**Use** 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
- mucus in the stool
- a history of liver disease

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

**Drug Facts (continued)**

Stop use and ask a doctor if symptoms get worse

- diarrhea lasts for more than 2 days

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.

**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 (46-59 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**

- do not use if pouch is open or torn
- store between 20-25C (68-77F)
- protect from light

**Inactive ingredients** acetamide K, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

**Questions or comments?**  
call 1-800-662-6357

McNeil Consumer Healthcare      www.imodium.com  
DIVISION OF MCNEIL-PPC, INC.  
FORT WASHINGTON, PA 19034 USA    MCNEIL-PPC, Inc. '86  
U.S. Patent Nos. 5,246,505 and 5,612,854

**Labeling Format Information:**

Fonts: Helvetica regular, bold and bold italic.

<b>Drug Facts:</b>	8.5 pt	<b>Leading:</b>	6.5 pt
<b>Header:</b>	8 pt	<b>Bullets:</b>	5 pt
<b>Subheader:</b>	6 pt	<b>Barlines:</b>	2.5 pt
<b>Body Text:</b>	6 pt	<b>Hairlines:</b>	0.5 pt
<b>Drug Facts (continued):</b>	8 pt		

Horizontal Scale: 85-87%      Average Kerning: -5

Keep out of reach of children.  
See important information on page 2.

# Imodium<sup>®</sup>

## ADVANCED

Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas

Easy to Swallow

**2 Caplets**

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

**Drug Facts**

**Active ingredient Purpose (in each caplet)**

Loperamide HCl 2 mg..... Anti-diarrheal

Simethicone 125 mg..... Anti-gas

**Use** 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
- mucus in the stool
- a history of liver disease

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

**Drug Facts (continued)**

**Stop use and ask a doctor if** ■ symptoms get worse ■ diarrhea lasts for more than 2 days

**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.

**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 (46-59 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**

- do not use if pouch is open or torn
- store between 20-25C (68-77F)
- protect from light

**Inactive ingredients** acetamide K, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

**Questions or comments?**  
call 1-800-962-5357

McNeil Consumer Healthcare  
DIVISION OF MCNEIL-PPC, INC.  
FORT WASHINGTON, PA 19034 USA ©MCH-PPC, Inc. '99  
U.S. Patent Nos. 5,240,505 and 5,612,854

**Labeling Format Information:**

Fonts: Helvetica regular, bold and bold italic.

<b>Drug Facts:</b>	8.5 pt		<b>Leading:</b>	6.5 pt
<b>Header:</b>	8 pt		<b>Bullets:</b>	5 pt
<b>Subheader:</b>	6 pt		<b>Barlines:</b>	2.5 pt
<b>Body Text:</b>	6 pt		<b>Hairlines:</b>	0.5 pt
<b>Drug Facts (continued):</b>	8 pt			

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Horizontal Scale: 85-87%      Average Kerning: -5

FOR PROFESSIONAL USE ONLY  
Not for Retail Sale

# Imodium<sup>®</sup>

**ADVANCED**  
Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas

# Imodium<sup>®</sup>

**ADVANCED**  
Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas

**NEW** Easy to Swallow

PATENTED FORMULA

Each caplet contains  
2 mg loperamide HCl and 125 mg simethicone

# Imodium<sup>®</sup>

**ADVANCED**  
Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

# Imodium<sup>®</sup>

**ADVANCED**  
Loperamide HCl/Simethicone  
**ANTI-DIARRHEAL/ANTI-GAS**

Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas

**NEW** Easy to Swallow

PATENTED FORMULA

Each caplet contains  
2 mg loperamide HCl and 125 mg simethicone

Pull Out Here

Controls the symptoms of diarrhea  
plus bloating, pressure, and cramps  
commonly referred to as gas

**NEW** Easy to Swallow

This unit  
contains **25 Pouches of 2 Caplets**

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

To be used by

Month Year

## Drug Facts

Active ingredient (in each caplet)	Purpose
Loperamide HCl 2 mg	Anti-diarrheal
Simethicone 125 mg	Anti-gas

### Use

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 ■ mucus in the stool ■ a history of liver disease

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

Stop use and ask a doctor if ■ symptoms get worse ■ diarrhea lasts for more than 2 days

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.

### 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

■ do not use if pouch is open or torn

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

■ see side panel for expiration date and lot number

### Inactive ingredients

acesulfame K, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

Questions or comments? call 1-800-962-5357



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FORT WASHINGTON, PA 19034 USA ©MCN-PPC, Inc.'00

XXXXXXXX  
U.S. Patent Nos. 5,248,505 and 5,612,054

### Labeling Format Information:

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	14 pt	Leading:	6.5 pt
Header:	8 pt	Bullets:	5 pt
Subheader:	6 pt	Barlines:	2.5 pt
Body Text:	6 pt	Hairlines:	0.5 pt
Drug Facts (continued):	0 pt		

Horizontal Scale: 100%

Average Kerning: 0



COPY

Date NOV 16 1988

**Imodium<sup>AD</sup>**  
**ADVANCED**  
 Loperamide HCl 2 mg  
 ANTI-DIARRHEAL/ANTI-DIA

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly related to diarrhea

**2 Caplets**

**SAMPLE • NOT TO BE SOLD**

Drug Facts	
<b>Active ingredient (in each caplet)</b>	<b>Purpose</b>
Loperamide HCl 2 mg	Anti-diarrheal
Diphenhydramine 125 mg	Anti-nausea
<b>Use:</b> Controls symptoms of diarrhea plus bloating, pressure, and cramps commonly related to diarrhea.	
<b>Warnings:</b> Allergic alerts: 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: • liver or kidney disease • a history of drug abuse Ask a doctor or pharmacist before use if you are taking anticholinergics.	

Drug Facts (continued)	
<b>Stop use and ask a doctor if:</b> • symptoms get worse • diarrhea lasts for more than 2 days • 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.	
<b>Directions:</b> • Drink plenty of clear fluids to help prevent dehydration caused by diarrhea. • Use 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 5-11 years (40-85 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 2-4 years (25-40 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 2 years (up to 47 lbs)	ask a doctor
<b>Other information:</b> • Do not use if pouch is open or torn. • Store between 20-25°C (68-77°F). • Keep from light.	
<b>Inactive ingredients:</b> acetaminophen, hydrocodone bitartrate, propylparaben, triacetin, sodium starch glycolate, stearic acid.	
<b>Questions or comments?</b> call 1-800-933-2337	
<small>             Merck Consumer Products              Division of Merck &amp; Co., Inc.              P.O. Box 2000, Kenilworth, NJ 07033              Tel: (201) 261-3300, ext. 2337              © 1988 Merck &amp; Co., Inc.           </small>	

**Labeling Format Information:**

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	8.5 pt	Leading:	6.5 pt
Header:	8 pt	Bullets:	5 pt
Subheader:	6 pt	Barlines:	2.5 pt
Body Text:	6 pt	Hairlines:	0.5 pt
Drug Facts (continued):	8 pt		

Horizontal Scale: 85-87%

Average Kerning: -5

COPY

54 NOV 16 1964

1. Tear Off a Section  
2. Fold Corner Inward and Peel Back Foil.

**Imodium**  
ADVANCED

EXP00000  
ABC123  
PORT WASHINGTON WA 98154 USA

1. Tear Off a Section  
2. Fold Corner Inward and Peel Back Foil.

**Imodium**  
ADVANCED

EXP00000  
ABC123  
PORT WASHINGTON WA 98154 USA

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1. Tear Off a Section  
2. Fold Corner Inward and Peel Back Foil.

**Imodium**  
ADVANCED

EXP00000  
ABC123  
PORT WASHINGTON WA 98154 USA



<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each caplet)</b></p> <p>Loperamide HCl 2 mg Simethicone 125 mg</p> <p><b>Purpose</b></p> <p>Anti-diarrheal Anti-gas</p> <p><b>Use</b></p> <p>Use to control symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas</p> <p><b>Warnings</b></p> <p>Do not use if you have ever had a rash or other allergic reaction to loperamide HCl</p> <p>Do not use if you have bloody or black stool</p> <p>Ask a doctor before use if you have ■ fever ■ mucus in the stool ■ a history of liver disease</p> <p>Ask a doctor or pharmacist before use if you are taking antibiotics</p> <p>Stop use and ask a doctor if ■ symptoms get worse ■ diarrhea lasts for more than 2 days</p> <p>If pregnant or breast-feeding, ask a health professional before use</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	<p><b>Directions</b></p> <p>■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea</p> <p>■ find right dose on chart. If possible, use weight to dose; otherwise, use age</p> <p>adults and children 2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours</p> <p>children 9-11 years (60-99 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</p> <p>children under 6 years (up to 47 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</p> <p>ask a doctor children 6-8 years (48-59 lbs)</p>
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**Imodium. ADVANCED**  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas

PATENTED FORMULA

**6 Caplets**

**Imodium. ADVANCED**  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

LOT: \_\_\_\_\_  
Exp: \_\_\_\_\_

**Imodium. ADVANCED**  
Loperamide HCl/Simethicone  
ANTI-DIARRHEAL/ANTI-GAS

Controls the symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas

**NEW Easy to Swallow**

**6 Caplets**

Each caplet contains 2 mg loperamide HCl and 125 mg simethicone

EASY TO OPEN PACKAGE

1. Tear Off 1 Section  
2. Fold Caplet in Half and Push Out

00000-00000-000

**Drug Facts (continued)**

**Other information**

■ do not use if carton or blister unit is open or torn

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

■ see side panel for expiration date and lot number

**Inactive ingredients**

lecithin K<sub>1</sub>, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid

**Questions or comments?** call 1-800-962-5357

**Labeling Format Information:**

Fonts: Helvetica regular, bold and bold italic.	
Drug Facts: 8.5 pt	Leading: 6.5 pt
Header: 8 pt	Bullets: 5 pt
Subheader: 6 pt	Barlines: 2.5 pt
Body Text: 6 pt	Hairlines: 0.5 pt
Drug Facts (continued): 8 pt	

Horizontal Scale: 85-95%      Average Kerning: -20

21-140      8/24/00