ATTACHMENT 2

2.5"

2 3/8" (2.375)

To Open: While Pressed on Lines, Tear At Slit

Drug Facts (continued)

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

3

Imodium® ANTI-DIARRHEAL Controls the Symptoms of Diarrhea

A-D Loperamide HCl **2 Caplets**

Each caplet contains 2 mg loperamide HCl

Drug Facts

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

Loperamide HCl 2 mg.....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

Open here to view complete product information

1

OUTSIDE PAGES

INSIDE PAGES

2

Drug Facts (continued)

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.

4

Drug Facts (continued)

Other information
- store between 20-25C (68-77F)
- do not use if pouch is opened

Inactive ingredients
colloidal silicon dioxide, D&C yellow no. 10, dibasic calcium phosphate, FD&C blue no. 1, magnesium stearate, microcrystalline cellulose

Questions or comments?
call 1-800-962-5357. Llámanos con preguntas: 1-888-466-8746

McNeil

McNeil Consumer Healthcare
DIVISION OF MCNEIL – PPC, INC.
FORT WASHINGTON, PA 19034 USA
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www.imodium.com

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Labeling Format Information:

Fonts: Helvetica bold, black, and black oblique

Drug Facts:	8.25 pt	**Leading**:	6.5 pt
Header:	8 pt	**Bullets**:	5 pt
Subheader:	6 pt	**Barlines**:	2.5 pt
Body Text:	6 pt	**Hairlines**:	.5 pt
Drug Facts (continued):	8 pt		

Horizontal Scale: 70-80% Average Kerning: 0

DE

77

100

FedEx Express USA Airbill

FedEx Tracking Number 8312 3906 7670

Form No. 0215

Recipient's Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 11/27/2001 FedEx Tracking Number 831239067670

Sender's Name MAUREEN BARRON Phone 215 273-7000

Company MCNEIL CONSUMER HEALTHCARE

Address 7050 CAMP HILL RD Dept./Floor/Suite/Room

City FORT WASHINGTON State PA ZIP 19034

2 Your Internal Billing Reference 016281174700000000

3 To

Recipient's Name Docket No. 98N-0337 Phone

Company Food and Drug Administration

Address 5630 Fishers Lane, Room 1061

To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

Dept./Floor/Suite/Room

City Rockville State MD ZIP 20852

8312 3906 7670

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4a Express Package Service *Packages up to 150 lbs.* Delivery commitment may be later in some areas.

- [x] FedEx Priority Overnight — Next business morning
- [ ] FedEx Standard Overnight — Next business afternoon
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [ ] FedEx 2Day — Second business day
- [ ] FedEx Express Saver — Third business day
- [ ] NEW FedEx Extra Hours — Later drop-off with next business afternoon delivery for select locations

FedEx Envelope rate not available. Minimum charge: One-pound rate

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

* Call for Confirmation: _____

5 Packaging * Declared value limit $500

- [x] FedEx Envelope*
- [ ] FedEx Pak* — Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak
- [ ] Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling Include FedEx address in Section 3.

- [ ] SATURDAY Delivery — Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- [ ] HOLD Weekday at FedEx Location — Not available for FedEx First Overnight
- [ ] HOLD Saturday at FedEx Location — Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [x] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Yes — Shipper's Declaration not required
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg

Dangerous Goods (incl. Dry Ice) cannot be shipped in FedEx packaging or with FedEx Extra Hours service.

- [ ] Cargo Aircraft Only

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below.

- [x] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check
- [ ] Obtain Recip. Acct. No.

[redacted]

Total Packages	Total Weight	Total Charges
		Credit Card Auth.

†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

8 Release Signature *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Visit our Web site at fedex.com or call 1.800.Go.FedEx® 800.463.3339.

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