CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-448

FINAL PRINTED LABELING

Labeling: [illegible]

NDA No: [illegible] Rc'd. [illegible]

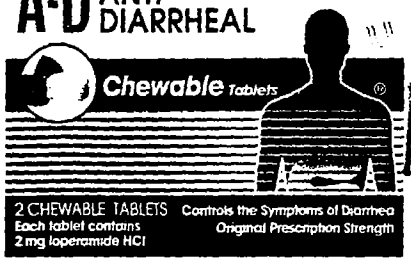
Reviewed by: [illegible]

Whilp folded on line, tear open at slit

Imodium®

Loperamide HCl

A-D ANTI-DIARRHEAL



2 CHEWABLE TABLETS Controls the Symptoms of Diarrhea

Each tablet contains Original Prescription Strength

2 mg loperamide HCl

11 11 2 4 1997

APPROVED

DO NOT USE IF POUCH IS OPENED. ACTIVE INGREDIENT: Loperamide HCl 2 mg. PURPOSE: Anti-diarrheal. USES: Controls the symptoms of diarrhea, including Travelers Diarrhea. DIRECTIONS: See the chart below for the correct dose: Chew the first dose and take with water after the first loose stool. If needed, chew the next dose and take with water after the next loose stool. Drink plenty of clear liquids to prevent dehydration.

DOSAGE	Age	First Dose	Next Doses	Maximum Number Per Day
Adults	12 yrs and over	2 tablets	1 tablet	4 tablets
Children	9–11 yrs (60–95 lbs)	1 tablet	1/2 tablet	3 tablets
	6–8 yrs (48–59 lbs)	1 tablet	1/2 tablet	2 tablets

Children under 6 years (48 lbs to 47 lbs): Consult a physician. Not intended for use in children under 6 years (48 lbs). WARNINGS: Do Not Use If: you have a high fever (over 101°F), blood or mucus in your stool, you have has a rash or other allergic reaction to Loperamide HCl. Do Not Use Without Asking A Doctor: for more than 2 days, if you are taking antibiotics, if you have a history of liver disease. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or call a poison control center immediately. PHENYLKETONURICS: CONTAINS PHENYLALANINE 3 mg PER TABLET. INACTIVE INGREDIENTS: Aspartame, basic butylmethacrylate, cellulose acetate, corn starch, flavors, magnesium stearate, menthol, microcrystalline cellulose, sucrose, D&C Yellow 10 and FD&C Blue 1. Store at 15–30°C (59–86°F). DIST. BY: McNEIL CONSUMER PRODUCTS CO., Div. of McNEIL-PPC, Inc., Fort Washington, PA 19034 USA ©McN-PPC, Inc. '97 9707054

EXP LOT

APPEARS THIS WAY
ON ORIGINAL

Labeling

NDA No: _____

Reviewed by: _____

APPROVED

24

09707051

Imodium® A-D ANTI-DIARRHEAL Loperamide HCl

Controls the Symptoms of Diarrhea, Including Travelers' Diarrhea.

6 CHEWABLE TABLETS

Chewable Tablets

Imodium®

A-D ANTI-DIARRHEAL

Loperamide HCl

NEW!

Chewable Tablets

6 CHEWABLE TABLETS

Each tablet contains 2 mg loperamide HCl

Controls the Symptoms of Diarrhea
Original Prescription Strength

EXP

LOT

Imodium® Loperamide HCl
A-D ANTI-DIARRHEAL
***Chewable** Tablets*

DO NOT USE IF CARTON IS OPENED OR IF SUCH SEAL IS BROKEN

Only from the makers of Imodium® A-D, Chewable Tablets:
- **are uniquely formulated and convenient to take anywhere**
- **contain the original prescription strength of Imodium® A-D for diarrhea relief, often in just one dose**

Imodium® Loperamide HCl
A-D ANTI-DIARRHEAL
***Chewable** tablets*

ACTIVE INGREDIENT: Loperamide HCl 2 mg • **PURPOSE:** Anti-diarrheal

USES • Controls the symptoms of diarrhea, including Travelers' Diarrhea

DIRECTIONS See the chart below for the correct dose
- Chew the first dose and take with water after the first loose stool
- If needed, chew the next dose and take with water after the next loose stool
- Drink plenty of clear liquids to prevent dehydration.

DOSAGE	Age	First Dose	Next Doses	Maximum Number Per Day
Adults	12 yrs and over	2 tablets	1 tablet	4 tablets
Children	9–11 yrs (60–95 lbs)	1 tablet	1/2 tablet	3 tablets
	6–8 yrs (48–59 lbs)	1 tablet	1/2 tablet	2 tablets

Children under 6 years old (up to 47 lbs): Consult a physician. Not intended for use in children under 6 years old.

WARNINGS
- **Do Not Use If:**
  - You have a high fever (over 101°F)
  - Blood or mucus in your stool
  - You have had a rash or other allergic reaction to Loperamide HCl
- **Do Not Use Without Asking A Doctor:**
  - For more than 2 days
  - If you are taking antibiotics
  - If you have a history of liver disease
  - As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product
- ***Keep this and all drugs out of the reach of children.***
- In case of accidental overdose, seek professional assistance or call poison control center immediately.
- PHENYLKETONURIC: CONTAINS PHENYLALANINE 3 mg PER TABLET

Store at 15–30°C (59–86°F)

INACTIVE INGREDIENTS: Aspartame, basic polymethacrylate, calcium acetate, corn starch, flavors, magnesium stearate, mannitol, microcrystalline cellulose, sucrose, D&C Yellow #10 and FD&C Blue #1

McNEIL

DISTRIBUTED BY:
McNEIL CONSUMER PRODUCTS CO.
DIVISION OF McNEIL-PPC, INC
FORT WASHINGTON, PA 19034 USA

© McN-PPC, Inc '97

3 0045-0365-06 4

Our first responsibility is to you and your family. That is why we guarantee that all IMODIUM® A-D products meet stringent demands for purity, quality and consistency. If you are not completely satisfied with this product, we will exchange it for another and refund all your choice or refund the purchase price.

IMODIUM A-D QUALITY

Tear at notch

For your family's protection, this package is child-resistant. Please follow instructions on the back side of the blister card to open. Do not force.

09707051