

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-232

APPROVED DRAFT LABELING

9 224 00 00 XA EXP. 5/97

TO OPEN:
1. Remove individual section
2. Tear section at notch

Loperamide Hydrochloride
Tablet, 2 mg
Anti-Diarrheal



MANUFACTURED BY PERMCO CO.
ALLEGAN, MI 49010, USA.

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JAN 6 1997

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EFB 185

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See side panel for expiration date. Store between 15-30°C (59-86°F).

ACTIVE INGREDIENTS: Loperamide HCl 2 mg per caplet.
INACTIVE INGREDIENTS: Carnauba wax, corn starch, D&C blue #1 aluminum lake, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol.

WARNINGS: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. Do not use for more than two days unless directed by a physician. DO NOT USE IF DIARRHEA IS ACCOMPANIED BY HIGH FEVER (GREATER THAN 101°F), OR IF BLOOD OR MUCUS IS PRESENT IN THE STOOL, OR IF YOU HAVE HAD A RASH OR OTHER ALLERGIC REACTION TO LOPERAMIDE HCl. If you are taking antibiotics or have a history of liver disease, consult a physician before using this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional immediately.

In case of accidental overdose, seek professional assistance or contact a poison control center.

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

AGE GROUP	1st dose	2nd dose, if needed
CHILDREN 6-8 YEARS (44-59 LBS)	Take 1 caplet after the first loose bowel movement and 1/2 caplet after each subsequent loose bowel movement but no more than 2 caplets a day for no more than 2 days.	☐
CHILDREN 9-11 YEARS (60-95 LBS)	Take 1 caplet after the first loose bowel movement and 1/2 caplet after each subsequent loose bowel movement but no more than 3 caplets a day for no more than 2 days.	☐
CHILDREN 12 YEARS OF AGE AND OLDER	Take 2 caplets after the first loose bowel movement and 1 caplet after each subsequent loose bowel movement but no more than 4 caplets a day for no more than 2 days.	☐

DIRECTIONS: Drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea.

INDICATIONS: Controls the symptoms of diarrhea, including "Travelers' Diarrhea."

• Easy to swallow, smaller caplets.
• One dose, in both adults and children 6 years and older.
• The original prescription strength of Loperamide Hydrochloride in a smaller caplet that is easier to swallow. This product is This product provides effective diarrhea relief in a smaller caplet that is easier to swallow. This product is

LOPERAMIDE HYDROCHLORIDE TABLETS, 2 MG ANTI-DIARRHEAL

Controls the symptoms
of diarrhea, including
"Travelers' Diarrhea"

Tear at notch



For your family's protection, this package is child resistant. Please follow instructions on the box as to the proper way to open it. If difficult to open, use a sharp knife.

ORIGINAL PRESCRIPTION STRENGTH IN SMALLER CAPLETS

Compare to Imodium®
Active Ingredient

DO NOT USE IF CARTON IS OPENED
OR IF A BLISTER UNIT IS BROKEN

NDC 0113-0224-53

LOPERAMIDE HYDROCHLORIDE TABLETS, 2 MG ANTI-DIARRHEAL



JAN 6 1980

Controls the Symptoms
of Diarrhea

12 CAPLETS*

*Each caplet (capsule-shaped tablet)
contains 2 mg loperamide hydrochloride

MANUFACTURED BY
PERRIGO
ALLEGAN, MI 49010 U.S.A.



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OPEN OTHER END

CONVENIENT RECLOSING TAB