







**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-232

APPROVED DRAFT LABELING

MAN

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| <p>9 224 00 00 XA 2 Tear section at notch 1 Remove individual section TO OPEN</p>  <p>Loperamide Hydrochloride Tablet, 2 mg Anti-Diarrheal</p> | <p>9 224 00 00 XA 2 Tear section at notch 1 Remove individual section TO OPEN</p>  <p>Loperamide Hydrochloride Tablet, 2 mg Anti-Diarrheal</p> | <p>9 224 00 00 XA EXP. 5/97 2 Tear section at notch 1 Remove individual section TO OPEN</p>  <p>Loperamide Hydrochloride Tablet, 2 mg Anti-Diarrheal</p> |
| <p>TEAR AT NOTCH</p> <p>← →</p> <p>← →</p> <p>TEAR AT NOTCH</p> | <p>TEAR AT NOTCH</p> <p>← →</p> <p>← →</p> <p>TEAR AT NOTCH</p> | <p>TEAR AT NOTCH</p> <p>← →</p> <p>← →</p> <p>TEAR AT NOTCH</p> |
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margin

MYLAR
EFB 185

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

ACTIVE INGREDIENTS: Loperamide HCl 2 mg per caplet.

INACTIVE INGREDIENTS: Canaflax wax, corn starch, D&C yellow #10 aluminum lake, FD&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 FLASH 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.

CHILDREN 6-8 YEARS (48-59 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.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER
 1st dose: 2nd dose, if needed:

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.

• 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.

For your family's protection, this package is child-resistant. Please follow instructions on the box and do not let the child 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 2006

Controls the Symptoms of Diarrhea

12 CAPLETS*

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

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OPEN OTHER END

CONVENIENT RECLOSING TAB

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



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