

Example Drug Facts Label for Loperamide HCl in a Tablet/Caplet Dosage Form

Drug Facts

| Active ingredient (in each [insert dosage unit]) | Purpose |
|---|----------------|
| Loperamide HCl 2 mg..... | Antidiarrheal |

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

Ask a doctor before use if you have

- # high fever (greater than 101⁰F)
 - # mucus present in your 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 diarrhea lasts for more than 2 days

[If applicable] Phenylketonurics: Contains Phenylalanine (_) mg Per (Dosage Unit)

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, which may accompany diarrhea
- # find right dose on chart. If possible, use weight to dose; otherwise, use age.
- [For chewable tablets] # chew each tablet and take with water

| | |
|---|---|
| adults and children 12 years and older | 2 tablets after the first loose bowel movement ¹ ; 1 tablet after each subsequent loose bowel movement; but no more than 4 tablets a day |
| children 9 - 11 years (60 - 95 lbs) | 1 tablet after the first loose bowel movement; 1/2 tablet after each subsequent loose bowel movement; but no more than 3 tablets a day |
| children 6 – 8 years (48 - 59 lbs) | 1 tablet after the first loose bowel movement; 1/2 tablet after each subsequent loose bowel movement; but no more than 2 tablets a day |

¹ The word “stool” may be used in place of the words “bowel movement” in the above table.

| | |
|---------------------------------------|---|
| children under 6 years (up to 47 lbs) | ask a doctor (not intended for use in children under 6 years old) |
|---------------------------------------|---|

Other information

optional – tamper evident statement

optional - storage conditions [that are appropriate for the product in both °C and °F]

optional – see [end or side] panel for lot number and expiration date

Inactive ingredients [list ingredients in alphabetical order]

Questions or comments? call toll free **1-800-XXX-XXXX**

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.