

Example Drug Facts Label for Loperamide HCl in a Liquid Dosage Form

Drug Facts

Active ingredient (in each 5 mL)	Purpose
Loperamide HCl 1 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
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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 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

- # use enclosed dosage cup to accurately measure dosage as noted below
- # 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.

adults and children 12 years and older	4 teaspoonfuls (1 dosage cup) after the first loose bowel movement ¹ ; 2 teaspoonfuls (1/2 dosage cup) after each subsequent loose bowel movement; but no more than 8 teaspoonfuls a day
children 9 – 11 years (60 - 95 lbs)	2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement; 1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement; but no more than 6 teaspoonfuls a day
children 6 – 8 years (48 – 59 lbs)	2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement; 1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement; but no more than 4 teaspoonfuls 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)
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Other information

optional – tamper evident statement

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

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.