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

**Drug Facts**

**Active ingredient (in each [insert dosage unit])**

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 101°F)
# 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

<table>
<thead>
<tr>
<th>Adults and children 12 years and older</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 9 - 11 years (60 - 95 lbs)</td>
<td>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</td>
</tr>
<tr>
<td>Children 6 – 8 years (48 - 59 lbs)</td>
<td>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</td>
</tr>
</tbody>
</table>

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