

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

Drug Facts

Active ingredient (in each 5 mL)**Purpose**

Loperamide HCl 1 mgAntidiarrheal

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 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

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

	loose bowel movement; but no more than 4 teaspoonfuls a day
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 ⁰ C and ⁰ 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.

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	1 tablet after the first loose bowel movement; 1/2 tablet after each

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

(48 - 59 lbs)	subsequent loose bowel movement; but no more than 2 tablets a day
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.

Example Drug Facts Label for Cimetidine 200 mg in a Tablet Dosage Form

Drug Facts

Active ingredient (in each tablet)	Purpose
Cimetidine 200 mg.....	Acid reducer

Uses

- # relieves heartburn associated with acid indigestion and sour stomach
 - # prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages.
-

Warnings

Allergy alert: Do not use if you are allergic to cimetidine or other acid reducers.

Do not use with other acid reducers

Ask a doctor before use if you have

- # trouble swallowing
 - # persistent abdominal pain
- See a doctor right away because you may have a serious condition that may need a different treatment.
-

Ask a doctor or pharmacist before use if you are taking

- # theophylline (oral asthma medicine)
 - # warfarin (blood thinning medicine)
 - # phenytoin (seizure medicine)
- If you are not sure whether you are taking one of these medicines, ask your doctor or pharmacist.
-

Stop use and ask a doctor if

- # you need to take this product for more than 2 weeks continuously
-

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

- # adults and children 12 years and older:
 - # to **relieve** symptoms, swallow 1 tablet with a glass of water

to **prevent** symptoms, swallow 1 tablet with a glass of water **right before or any time up to 30 minutes before** eating food or drinking beverages that cause heartburn

can be used up to twice daily (up to 2 tablets in 24 hours)

children under 12 years: ask a doctor

Other information

optional - tamper evident statement

optional - storage conditions [that are appropriate for the product in both ⁰ C and ⁰ 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.

Example Drug Facts Label for Acetaminophen 120 mg in a Suppository Dosage Form

Drug Facts

Active ingredient (in each rectal suppository)	Purposes
Acetaminophen 120 mg.....	Pain reliever/fever reducer

Uses temporarily # reduces fever # relieves minor aches, pains, and headache

Warnings
For rectal use only

Stop use and ask a doctor if

- # fever lasts more than 3 days (72 hours), or recurs
 - # you need to use this product for pain for more than 5 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.
-

Keep out of reach of children. If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for children even if you do not notice any signs or symptoms.

Directions¹

- # **do not use more than directed**
 - # remove foil wrapper
 - # insert suppository well up into rectum
 - # children 3 – 6 years:
 - # 1 suppository every 4 to 6 hours while symptoms persist
 - # do not exceed 6 suppositories in any 24-hour period
 - # children under 3 years: ask a doctor
-

Other information

- # optional - tamper evident statement
 - # store at 8-25⁰ C (46-77⁰ F)² or refrigerate
 - # optional - see [end or side] panel for lot number and expiration date
-

Inactive ingredients [list ingredients in alphabetical order]

¹ The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the first three bulleted statements appearing above the top line of the table.

² These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their NDA/ANDA to support storage up to 27⁰ C (80⁰ F) may use these temperatures in place of 25⁰ C (77⁰ F).

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.

Example Drug Facts Label for Acetaminophen 325 mg in a Suppository Dosage Form

Drug Facts

Active ingredient (in each rectal suppository)	Purposes
Acetaminophen 325 mg.....	Pain reliever/fever reducer

Uses temporarily # reduces fever # relieves minor aches, pains, and headache

Warnings

For rectal use only

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use in children under 6 years

Stop use and ask a doctor if

- # fever lasts more than 3 days (72 hours), or recurs
 - # you need to use this product for pain for more than 10 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.
-

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

Directions

do not use more than directed

- # remove foil wrapper
- # insert suppository well up into rectum

adults and children 12 years and older	2 suppositories every 4 to 6 hours while symptoms persist; do not exceed 12 suppositories in any 24-hour period
children 6 -12 years	1 suppository every 4 to 6 hours while symptoms persist; do not exceed 6 suppositories in any 24-hour period
children under 6 years	Do not use

Other information

- # optional - tamper evident statement
 - # store at 8-25⁰ C (46-77⁰ F)¹ or refrigerate
-

¹ These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their NDA/ANDA to support storage up to 27⁰ C (80⁰ F) may use these temperatures in place of 25⁰ C (77⁰ F).

Footnotes continue on the next page

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.

Example Drug Facts Label for Acetaminophen 650 mg in a Suppository Dosage Form

Drug Facts

Active ingredient (in each rectal suppository)	Purposes
Acetaminophen 650 mg.....	Pain reliever/fever reducer

Uses temporarily # reduces fever # relieves minor aches, pains, and headache

Warnings

For rectal use only

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use in children under 12 years

Stop use and ask a doctor if

- # fever lasts more than 3 days (72 hours), or recurs
 - # you need to use this product for pain for more than 10 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.
-

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

Directions¹

- # **do not use more than directed**
 - # remove foil wrapper
 - # insert suppository well up into rectum
 - # adults and children 12 years and older:
 - # 1 suppository every 4 to 6 hours while symptoms persist
 - # do not exceed 6 suppositories in any 24-hour period
 - # **children under 12 years: do not use**
-

Other information

- # optional - tamper evident statement

¹ The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the first three bulleted statements appearing above the top line of the table.

store at 8-25⁰ C (46-77⁰ F)² or refrigerate

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.

² These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their NDA/ANDA to support storage up to 27⁰ C (80⁰ F) may use these temperatures in place of 25⁰ C (77⁰ F).