

Attachment C

Proposed Labeling

DRUG FACTS

Active ingredient (in each strip)	Purpose
Loperamide HCL 2mg	Anti-diarrheal

Use – controls symptoms of diarrhea, including Travelers' Diarrhea

Warnings –

Allergy Alert: Do not use if you have ever had a rash or allergic reaction to loperamide HCL

Do not use if you have bloody or black stool

Ask a doctor before use if you have

- Fever
- Mucus in the stool
- A history of liver disease

Ask a doctor or pharmacist before using if you are

- Taking antibiotics

When using this product

- Tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

Stop use and ask a doctor if

- Symptoms get worse
- Diarrhea lasts for more than 2 days
- You get abdominal swelling or bulging. These may be signs of a serious condition.

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 prevent dehydration caused by diarrhea

Adults and children 12 years and over - dissolve two (2) strips in mouth after first loose stool; 1 strip after each subsequent loose stool, but no more than four (4) strips in 24 hours.

Children 9-11 years (60-95 lbs) - dissolve one (1) strip in mouth after first loose stool; 1/2 strip after each subsequent loose stool, but no more than three (3) strips in 24 hours.

Children 6-8 years (48-59 lbs) - dissolve one (1) strip in mouth after first loose stool; 1/2 strip after each subsequent loose stool, but no more than two (2) strips in 24 hours.

Children under 6 years (up to 47 lbs) - ask a doctor.

Other information

Each thin strip contains XX mg sodium

Read the directions and warning before use

Store at 20C-25C (68-77F)

Tamper Evident Packaging

Do not use if carton or foil pouch is open or torn

See side panel for lot number and expiration date

Inactive Ingredients

[Information will be included in the ANDA when submitted]

Questions or comments?

Call 1-XXX-XXX-XXXX