

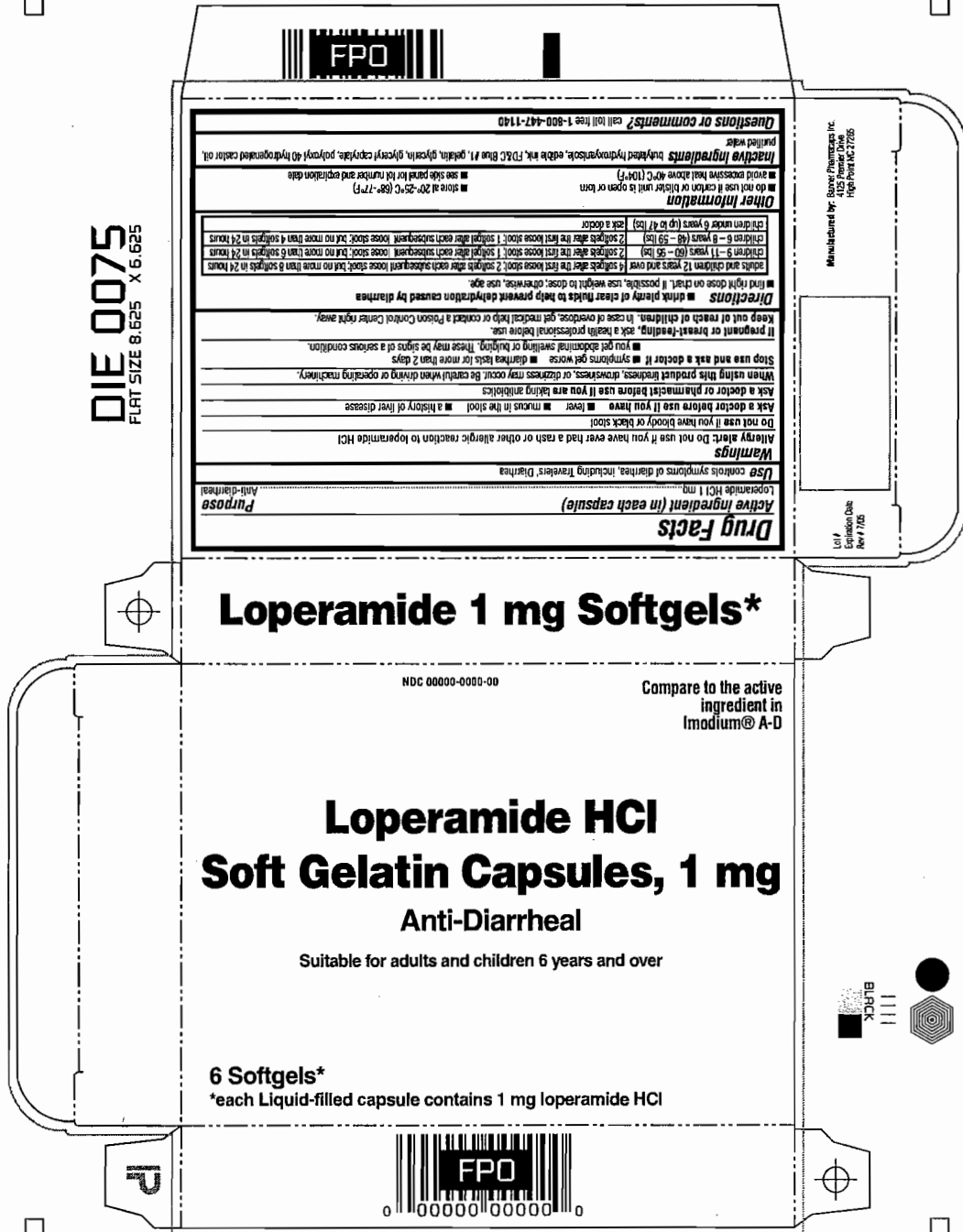
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-855

LABELING

DIE 0075
FLAT SIZE 8.625 X 6.625



CARTON

Approved By: _____

Date: _____

12 of 5
PP#



Drug Facts

Active ingredient (in each capsule)
Loperamide HCl 1 mg

Purpose
Anti-diarrheal

Warnings
Many have died. 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.
Do not use if you have been told by a doctor that you have a heart condition.
Ask a doctor or pharmacist before use if you are taking antacids.
When using this product, dizziness, drowsiness, or weakness may occur. Be careful when driving or operating machinery.
Stop use and ask a doctor if:
• symptoms get worse
• you get abdominal pain or cramping
• you get a rash or other allergic reaction
• you get a fever
• you get a headache
• you get a sore throat
• you get a change in voice
• you get a change in taste
• you get a change in vision
• you get a change in hearing
• you get a change in smell
• you get a change in taste
• you get a change in vision
• you get a change in hearing
• you get a change in smell

Directions
• Adults and children 12 years and over: 2 capsules after the first loose stool, 2 capsules after each subsequent loose stool, but no more than 8 capsules in 24 hours.
• Children 6 to 11 years (50 to 65 lbs): 1 capsule after the first loose stool, 1 capsule after each subsequent loose stool, but no more than 6 capsules in 24 hours.
• Children 2 to 5 years (25 to 45 lbs): 1 capsule after the first loose stool, 1 capsule after each subsequent loose stool, but no more than 4 capsules in 24 hours.
• Ask a doctor if you are taking other medicines, especially those that contain loperamide HCl.

Other information
• Do not use if you are taking other medicines, especially those that contain loperamide HCl.
• Do not use if you are taking other medicines, especially those that contain loperamide HCl.
• Do not use if you are taking other medicines, especially those that contain loperamide HCl.



Lot #
Expiration Date
Rev 7/105

Compare to the active ingredient in Imodium® A-D

Loperamide HCl
Soft Gelatin Capsules, 1 mg
Anti-Diarrheal

Suitable for adults and children 6 years and over

72 Softgels*
*each Liquid-filled capsule contains 1 mg loperamide HCl

Compare to the active ingredient in Imodium® A-D

Loperamide HCl
Soft Gelatin Capsules, 1 mg
Anti-Diarrheal

Suitable for adults and children 6 years and over

72 Softgels*
*each Liquid-filled capsule contains 1 mg loperamide HCl

Drug Facts (continued)

Other information
• Do not use if you are taking other medicines, especially those that contain loperamide HCl.
• Do not use if you are taking other medicines, especially those that contain loperamide HCl.
• Do not use if you are taking other medicines, especially those that contain loperamide HCl.

Questions or comments? call toll free 1-800-447-1742

Manufactured by: Bannett Pharmaceuticals Inc.
4125 Pymont Drive
High Point NC 27285

FPO

DIE 0075
FLAT SIZE 8.625 X 6.625

Drug Facts

Active ingredient (in each capsule)
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 other allergic reaction to loperamide HCl
Do not use if you have bloody or black stool or in children under 12 years of age (see *Other Information*)
Ask a doctor or pharmacist before use if you have fever, mucus in the stool, or a history of liver disease
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 or diarrhea lasts for more than 2 days
If you get abdominal swelling or bloating. 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 help prevent dehydration caused by diarrhea
■ not for use in children under 12 years of age
■ adults and children 12 years and over: 2 softgels after the first loose stool, but no more than 4 softgels in 24 hours

Other Information
■ do not use if carton or blister unit is open or torn
■ avoid excessive heat above 40°C (104°F)
■ use the 1 mg soft gelatin capsule product for children 6 to under 12 years of age
■ see side panel for lot number and expiration date
■ store at 20°-25°C (68°-77°F)

Inactive ingredients butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified water

Questions or comments? call toll free 1-800-447-1140

Manufactured by: Banner Pharmaceuticals Inc.
4125 Premier Drive
High Point NC 27265

Lot #
Expiration Date
Rev # 7/05

Loperamide 2 mg Softgels*

NDC 00-0000-000000

Compare to the active
ingredient in
Imodium® A-D

Loperamide HCl

Soft Gelatin Capsules, 2 mg

Anti-Diarrheal

Suitable for adults and children 12 years and over

6 Softgels*

*each Liquid-filled capsule contains 2 mg loperamide HCl



CARTON



Approved By: _____

Date: _____

BLACK

VARNISH

— 100 —



Lot #
Expiration Date
Buy 1/7/05

MDC 00000-00000-00

U

Suitable for adults and children 12 years and over

72 Softgels*
*each Liquid-filled capsule contains 2 mg loperamide HCl

NDC 00009-0038-00

**Loperamide
2 mg Softgels***

Suitable for adults and children 12 years and over

72 Softgels*
*each Liquid-filled capsule contains 2 mg loperamide HCl

Manufactured by: Bayer Pharmaceuticals Inc.
4125 Pfeiffer Drive
High Point NC 27265

Drug Facts (continued)
Inactive ingredients: butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxy-40 hydrogenated castor oil, purified water

Questions or comments? call toll free 1-800-447-1140