

2 CAPLETS

Imodium

ADVANCED

Loperamide Hydrochloride
ANTIDIARRHEAL/ANTI-GAS

Controls the symptoms of diarrhea
plus bloating, pressure, and cramps
commonly referred to as gas

2 Caplets

SAMPLE NOT TO BE SOLD

Drug Facts	
Active Ingredient (in each caplet)	Purpose
Loperamide HCl 2 mg	Anti-diarrheal
Simethicone 125 mg	Anti-gas
Use Controls symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas.	
Warnings	
Do not use if you have ever had a seizure or other allergic reaction to loperamide HCl.	
Do not use if you have bloody or black stool.	
Do not use before use if you have or have had a seizure in the stool.	
Do not use if you have a fever.	
Do not use if you are taking other medicines.	
Do not use if you are taking other medicines.	

Drug Facts (continued)	
Stop use and ask a doctor if symptoms get worse.	
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	
Drink plenty of clear fluids to help prevent dehydration caused by diarrhea.	
Find right dose on chart. If possible, use weight to dose; otherwise, use age.	
adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 5 caplets in 24 hours
children 6-8 years (46-69 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor
Other Information	
Store between 20-25C (68-77F).	
Protect from light.	
Do not use if pouch is open or torn.	
Inactive Ingredients acetaminophen K, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, talc, etc.	
Questions or comments? Call 1-800-442-2227	

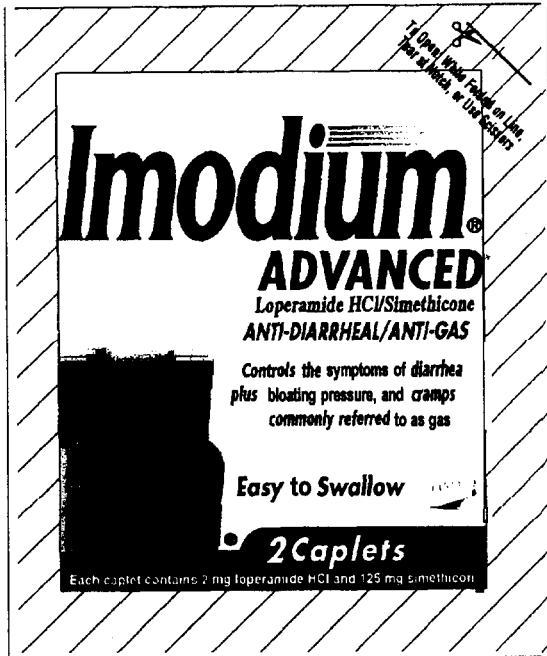
NDA 21-140
SLR 002

10-14-02

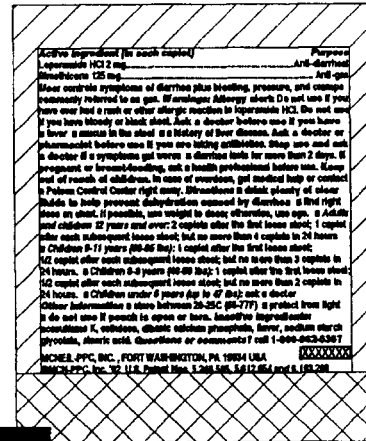
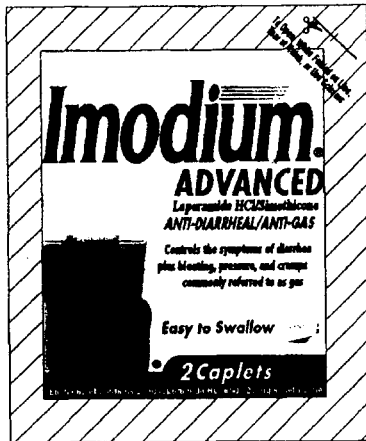
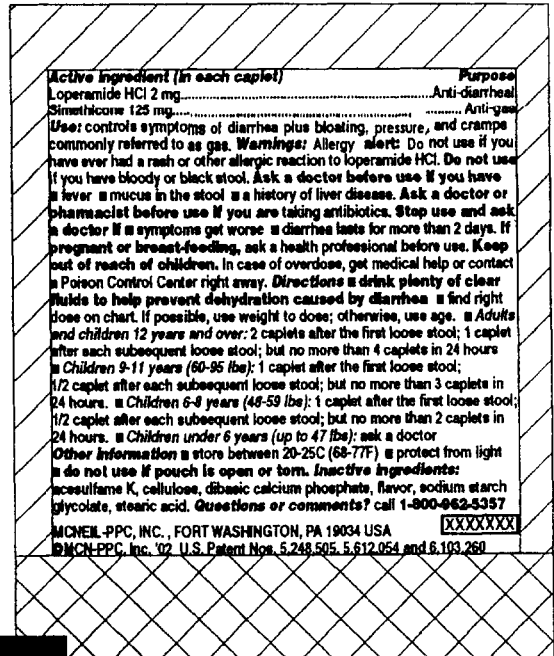
Double Pouch

2-count

labeling (prior approved)



150% OF SIZE



NDA 21-140
 SLR 002
 10/14/02
 2-count single
 pouch labeling
 (Proposed)

Labelina Format Information:			
Fonts: Helvetica regular, bold and bold italic.			
Drug Facts:	NA	Leading:	4.7 pt
Header:	4.5 pt	Bullets:	3.5 pt
Subheader:	4.5 pt	Barlines:	NA
Body Text:	4.5 pt	Hairlines:	NA
Drug Facts (continued):	NA		
Horizontal Scale: 78%		Average Kerning: -10	