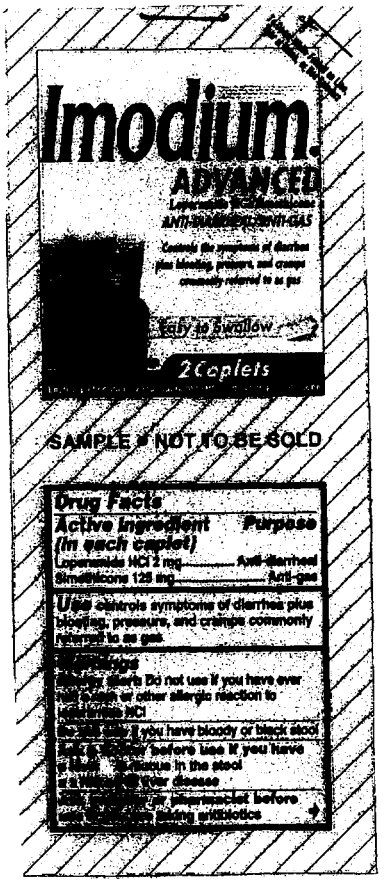
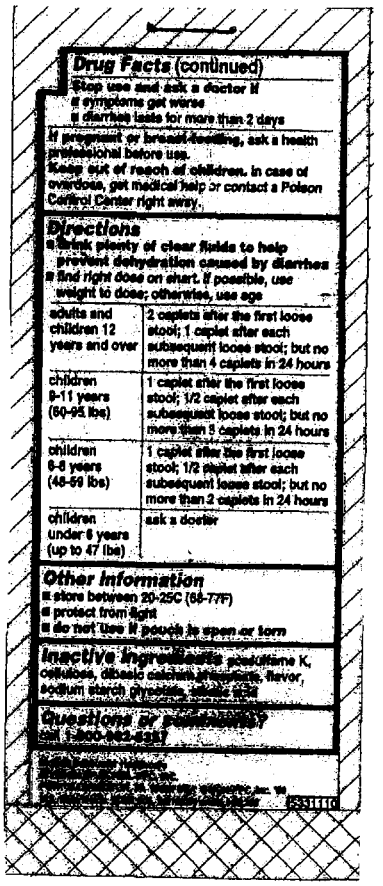
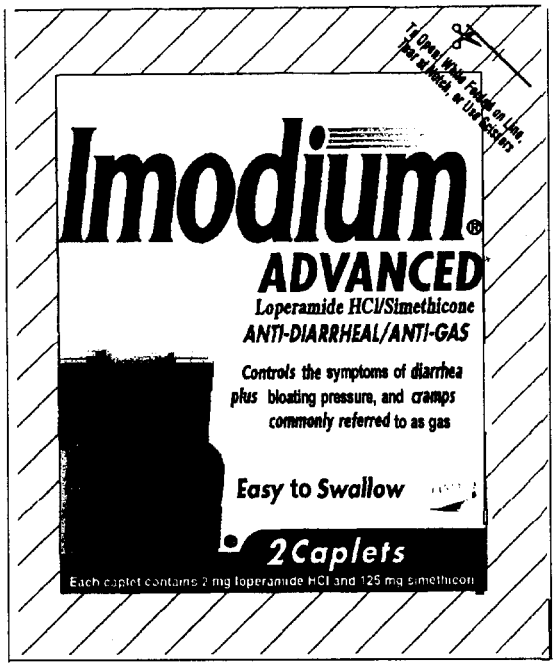
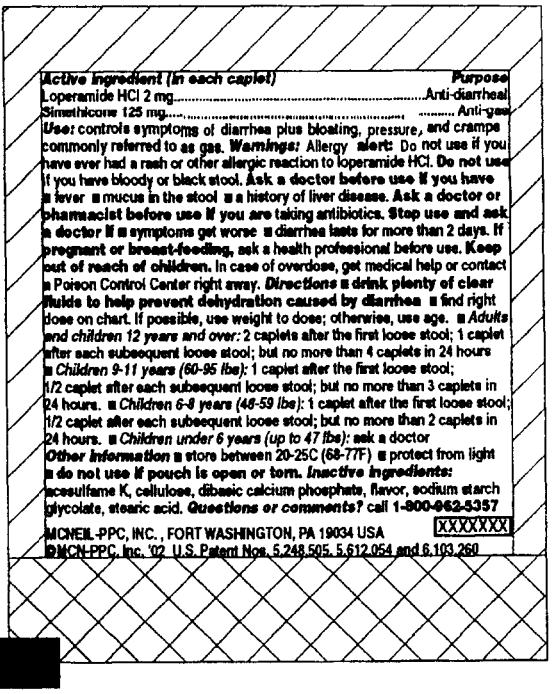




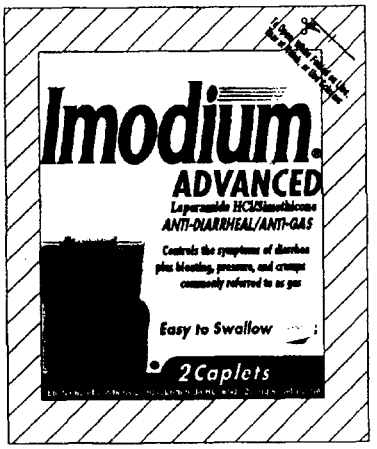
NDA 21-140
SLR 002
10-14-02
Double Pouch
2-count
labeling (prior approved)

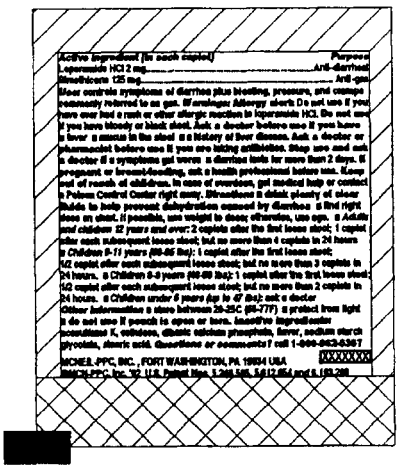


150% OF SIZE



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:** 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** ■ fever ■ mucus in the 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** ■ symptoms get worse ■ 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 3 caplets in 24 hours. ■ *Children 6-8 years (48-59 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:** acesulfame K, cellulose, dibasic calcium phosphate, flavor, sodium starch glycolate, stearic acid. **Questions or comments?** call **1-800-962-5357**
MCNEIL-PPC, INC., FORT WASHINGTON, PA 19034 USA XXXXXXX
©MCN-PPC, Inc. '02 U.S. Patent Nos. 5,248,505, 5,612,054 and 6,103,260





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	

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AUGUST 27, 2002