ANTIDIARRHEAL RELIEF- loperamide hcl tablet
Honeywell Safety Products USA, Inc

0498-1071: Antidiarrheal

Active ingredient (in each caplet)

Loperamide HCl USP 2 mg

Purpose

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

Heart attack: taking more than directed can cause serious heart problems or death

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.

When using this product

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

Stop use and ask a doctorif

- diarrhea lasts for more than 2 days
- symptoms get worse
- you get abdominal swelling or bulging.

These may be signsor 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.

Do not use if individual packet is torn or open.

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 (60-95lbs) 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(48-59lbs) 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

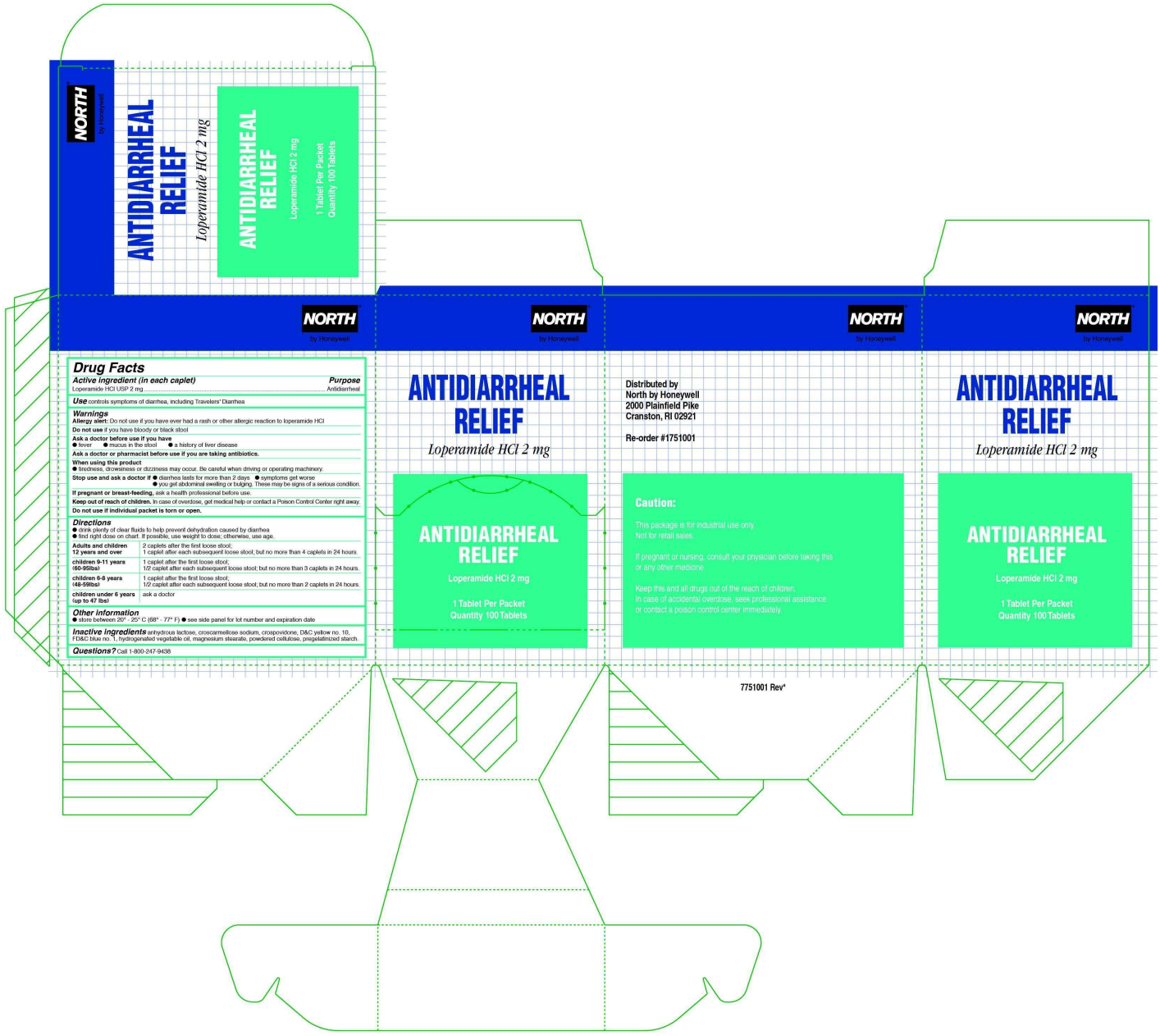
Inactive ingredients

anhydrous lactose, croscarmellose sodium, crospovidone, D&C yellow #10, FD&C blue #1, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

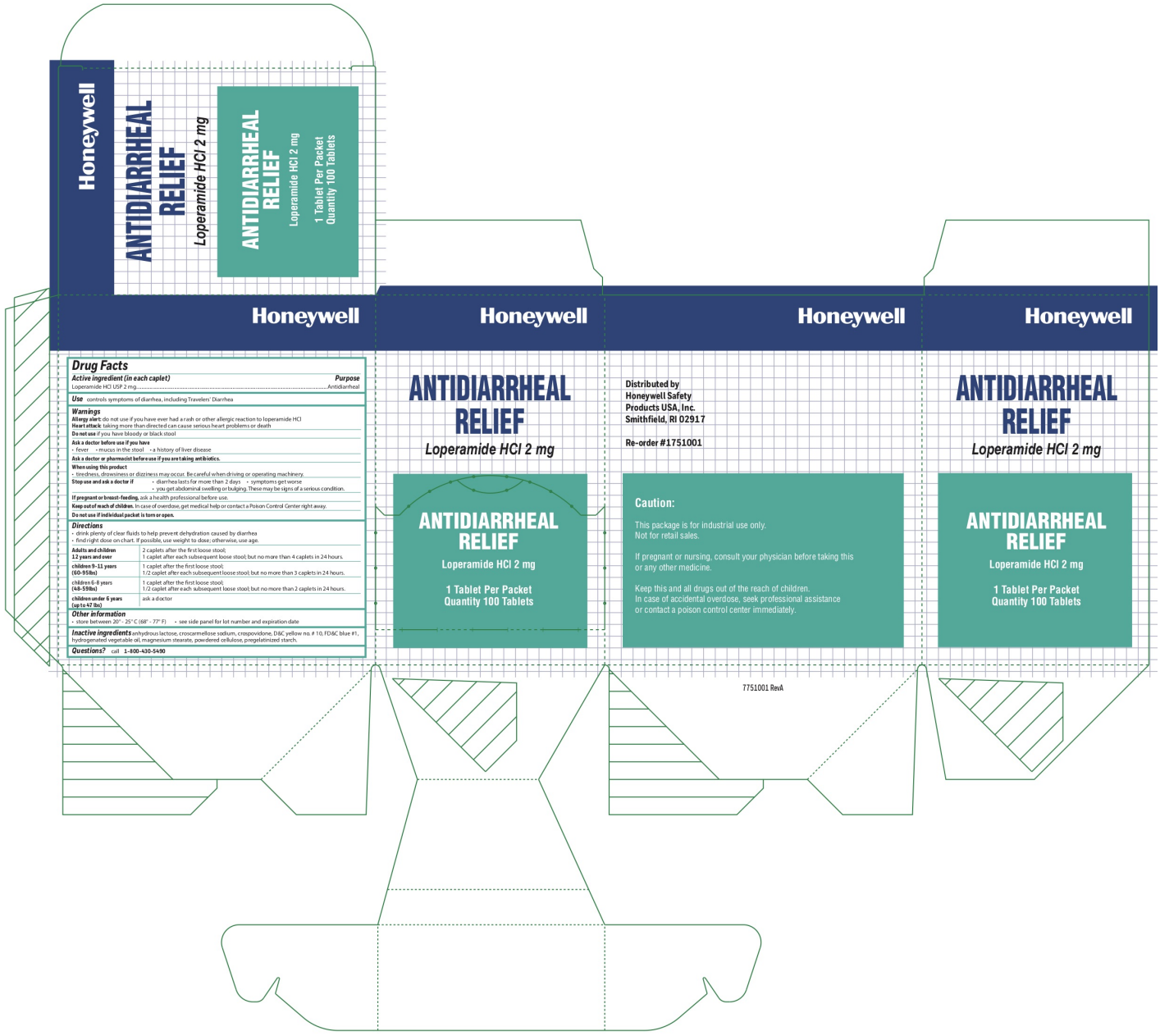
Questions?

call **1-800-430-5490**

MM1



Antidiarrheal Label



ANTIDIARRHEAL RELIEF

loperamide hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-1071
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CORN OIL (UNII: 8470G57WFM)	

Product Characteristics

Color	green (Bright Green)	**Score**	2 pieces
Shape	CAPSULE	**Size**	10mm
Flavor		**Imprint Code**	123
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-1071-07	100 in 1 CARTON	11/07/2018	
1	NDC:0498-1071-00	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074091	04/29/2013	

Labeler - Honeywell Safety Products USA, Inc (118768815)

Registrant - Honeywell Safety Products USA, Inc (118768815)

Establishment

Name	Address	ID/FEI	Business Operations
OHM LABORATORIES INC.		184769029	manufacture(0498-1071)