

**STOMACH RELIEF ANTI DIARRHEAL - loperamide hydrochloride tablet**  
**Select Corporation**

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**Drug Facts**

**ACTIVE INGREDIENT**

Loperamide HCl 2 mg

**PURPOSE**

Anti Diarrheal

**DOSAGE**

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

**INDICATIONS & USAGE**

• controls the 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
- if you have bloody or black stool Ask a doctor before use
- if you have: • fever • mucus in 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 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

## PREGNANCY

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

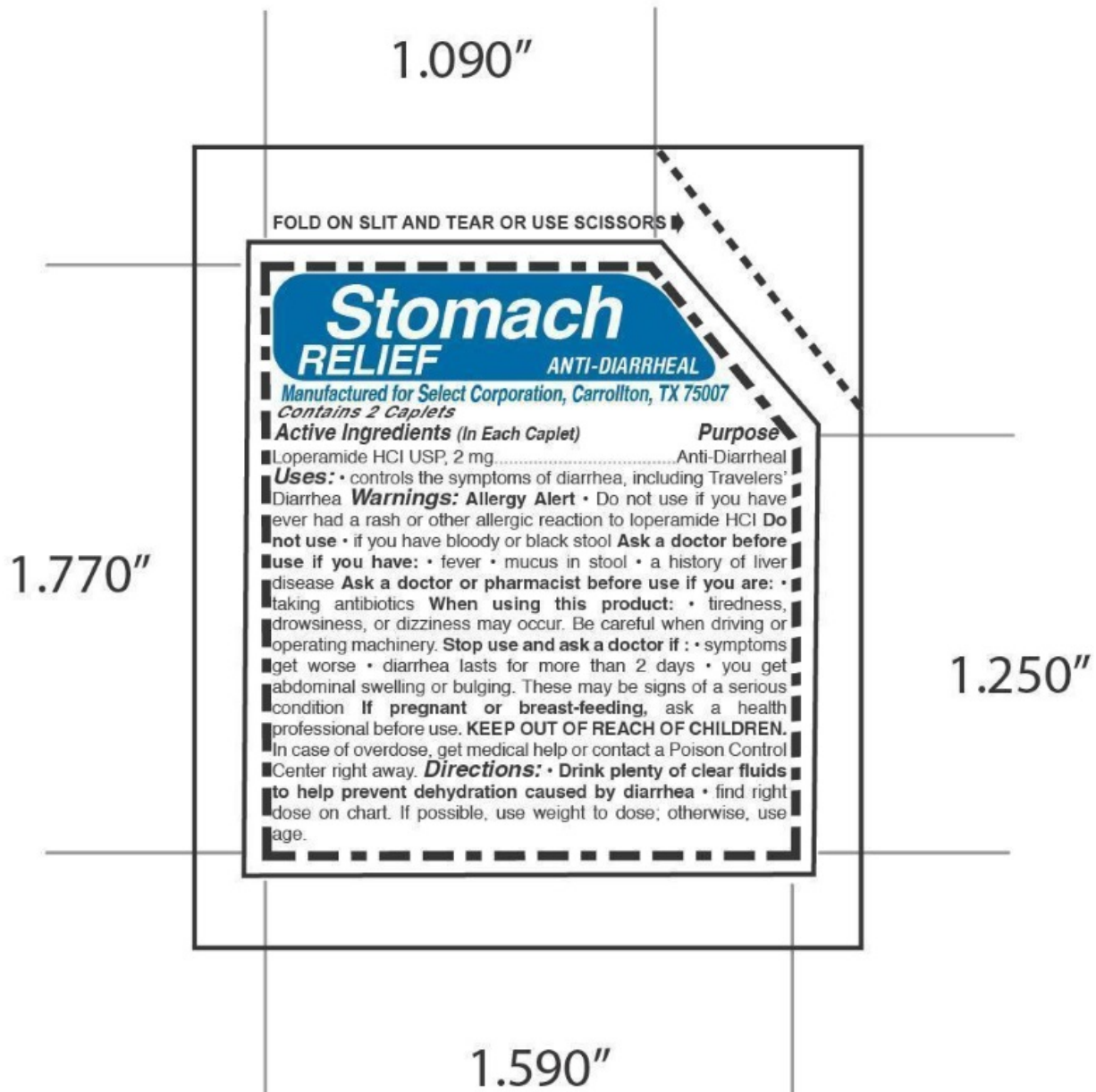
## INACTIVE INGREDIENT

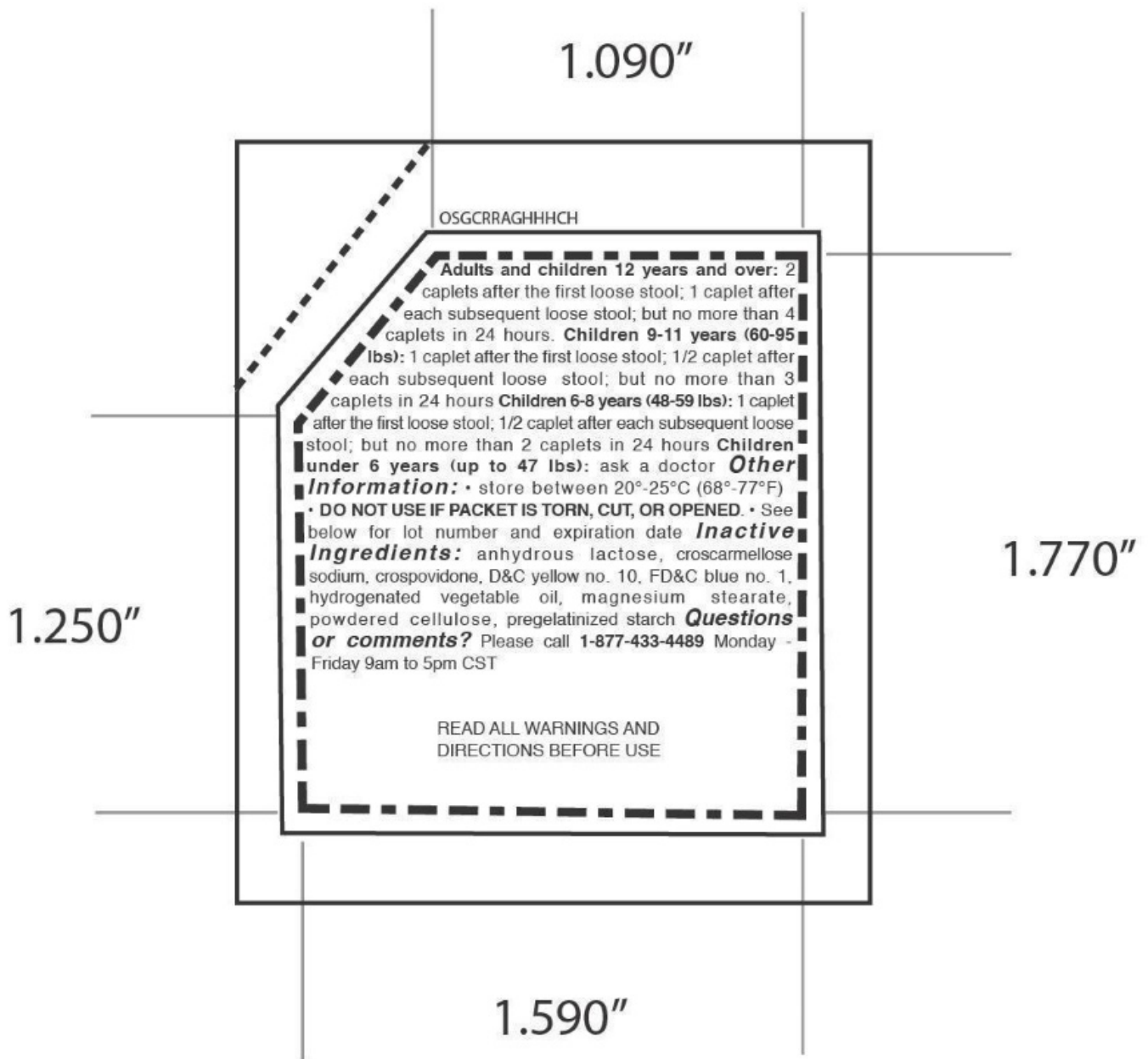
Inactive

Ingredients: anhydrous lactose, croscarmellose sodium, crospovidone, DC yellow no. 10, FDC blue no. 1, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

## LABEL DISPLAY PANEL

MM1





## STOMACH RELIEF ANTI DIARRHEAL

loperamide hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52904-443
<b>Route of Administration</b>	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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STARCH, CORN (UNII: O8232NY3SJ)	

**Product Characteristics**

Color	green (pea green)	Score	no score
Shape	CAPSULE (123)	Size	10mm
Flavor		Imprint Code	123
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-443-50	25 in 1 BOX	10/15/2012	
1	NDC:52904-443-06	1 in 1 CARTON		
1	NDC:52904-443-02	2 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	10/15/2012	

**Labeler** - Select Corporation (053805599)**Establishment**

Name	Address	ID/FEI	Business Operations
Select Corporation		053805599	label(52904-443)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(52904-443)

