#### SMART SENSE LOPERAMIDE HYDROCHLORIDE- loperamide hcl suspension Kmart Corporation

-----

# Kmart Corporation Loperamide Hydrochloride Oral Suspension Drug Facts

#### Active ingredient (in each 7.5 mL)

Loperamide HCl 1 mg

#### Purpose

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

#### 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 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.

# 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. (1-800-222-1222)

# 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.
- shake well before using
- only use attached measuring cup to dose product

adults and children	30 mL (6 tsp) after the first loose stool; 15 mL (3 tsp) after each subsequent loose stool; but no more than 60 mL (12 tsp) in 24 hours
12 years and over	
children 9-11 years (60-95 lbs)	15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 45 mL (9 tsp) in 24 hours
children 6-8 years (48-59 lbs)	15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 30 mL (6 tsp) in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor

# Other information

- each 30 mL (6 tsp) contains: sodium 15 mg
- store between 20-25°C (68-77°F)
- see side panel for lot number and expiration date

# **Inactive ingredients**

anhydrous citric acid, carboxymethylcellulose sodium, D&C yellow no. 10, FD&C blue no. 1, glycerin, microcrystalline cellulose, natural and artificial mint flavor, propylene glycol, purified water, simethicone, sodium benzoate, sucralose, titanium dioxide, xanthan gum

#### Questions or comments?

1-800-719-9260

# Package/Label Principal Display Panel

Compare to Imodium® A-D active ingredient Loperamide Hydrochloride Oral Suspension Anti-Diarrheal Controls the Symptoms of Diarrhea 1 mg Loperamide Hydrochloride per 7.5 mL 4 FL OZ (120 mL) Mint Flavor



Drug Facts (continued) Ask a doctor before use if you have ■ fever	Drug Facts (continued) Control Center right away. (1-800-222-1222) 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. ■ shake well before using ■ only use attached measuring cup to dose product		
■ 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 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.	· · ·	30 mL (6 tsp) after the first loose stool; 15 mL (3 tsp) after each subsequent loose stool; but no more than 60 mL (12 tsp) in 24 hours	
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	children 9-11 years (60-95 lbs)	15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 45 mL (9 tsp) in 24 hours ►	

	JUUU		$\left  \right\rangle$
		Drug Facts (continued) see side panel for lot number and	
(48-59 lbs)	loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose	expiration date	
	stool; but no more than 30 mL (6 tsp) in 24 hours	<i>Inactive ingredients</i> anhydrous citric acid, carboxymethylcellulose sodium, D&C yellow no. 10, FD&C blue no. 1, glycerin,	
children under 6 years (up to 47 lbs)	ask a doctor	microcrystalline cellulose, natural and artificial mint flavor, propylene glycol, purified water, simethicone, sodium benzoate, sucralose,	
Other information each 30 mL (6 tsp) contains: sodium 15 mg		titanium dioxide, xanthan gum <i>Questions or comments?</i> 1-800-719-9260	

Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source) NDC		NDC:497	2:49738-645	
Route of Administration	ORAL					
Active Ingredient/Active M	oietv					
0	gredient Name		Basis of Stre	ngth	Strength	
LOPERAMIDE HYDROCHLORIDE UNII:6X9OC3H4II)		-	LOPERAMIDE HYDROCHLORIDE	5	1 mg in 7.5 mL	
Inactive Ingredients	In and it at Norma				Street	
ANHYDRO US CITRIC ACID (UNII:	Ingredient Name				Strength	
CARBOXYMETHYLCELLULOSE S						
D&C YELLOW NO. 10 (UNII: 35SW						
FD&C BLUE NO. 1 (UNII: H3R47K3'						
GLYCERIN (UNII: PDC6A3C0OX)						
CELLULOSE, MICROCRYSTALLI	INE (UNII: OP1R32D61U)					
-						
PROPYLENE GLYCOL (UNII: 6 DC	9Q167V3)					
	9Q167V3)					
PROPYLENE GLYCOL (UNII: 6 DC						
PROPYLENE GLYCOL (UNII: 6DC WATER (UNII: 059QF0KO0R)	FE5EU)					
PROPYLENE GLYCOL (UNII: 6DC WATER (UNII: 059QF0KO0R) SODIUM BENZOATE (UNII: 0J245)	FE5EU)					
PROPYLENE GLYCOL (UNII: 6DC WATER (UNII: 059QF0KO0R) SODIUM BENZOATE (UNII: 0J245) SUCRALOSE (UNII: 96K6UQ3ZD4)	FE5EU) V2JP)					

Color		GREEN (opaque, viscous)	Score	
Shape			Size	
Flavor		MINT	Imprint Code	
Contains				
Packaging				
# Item C	ode	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49738-	-645-26	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 5/14/20 12	
2 NDC:49738	-645-34	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2014	
Marketin	g Info	ormation		
Marketing C	ategory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA091292	05/14/2012	

# Labeler - Kmart Corporation (008965873)

Revised: 1/2018

Kmart Corporation