### SMART SENSE IBUPROFEN- ibuprofen suspension Kmart Corporation

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### **Kmart Corporation Children's Ibuprofen Oral Suspension Drug Facts**

### Active ingredient (in each 5 mL = 1 teaspoonful)

Ibuprofen 100 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

### **Purposes**

Pain reliever/fever reducer

### Uses

temporarily:

- relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- reduces fever

### **Warnings**

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if your child:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- takes more or for a longer time than directed

Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

### Do not use

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

### Ask a doctor before use if

- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- child has high blood pressure, heart disease, liver cirrhosis, or kidney disease
- child has asthma
- child is taking a diuretic

### Ask a doctor or pharmacist before use if the child is

- under a doctor's care for any serious condition
- taking any other drug

### When using this product

- give with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

### Stop use and ask a doctor if

- child experiences any of the following signs of stomach bleeding
- feels faint
- vomits blood
- has bloody or black stools
- has stomach pain that does not get better
- the child does not get any relief within first day (24 hours) of treatment
- fever or pain gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

### 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**

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- shake well before using
- find right dose on chart. If possible, use weight to dose; otherwise use age.

- use only enclosed measuring cup
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

Dosing Chart			
Weight (lbs)	Age (yrs)	Dose (teaspoonful or mL)	
under 2 years		ask a doctor	
24-35 lbs	2-3 years	1 tsp or 5 mL	
36-47 lbs	4-5 years	1 1/2 tsp or 7.5 mL	
48-59 lbs	6-8 years	2 tsp or 10 mL	
60-71 lbs	9-10 years	2 1/2 tsp or 12.5 mL	
72-95 lbs	11 years	3 tsp or 15 mL	

### Other information

- each teaspoon contains: sodium 2 mg
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not freeze
- see bottom panel for lot number and expiration date

### **Inactive ingredients**

anhydrous citric acid, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

### Questions or comments?

1-800-719-9260

### **Principal Display Panel**

Compare to the active ingredient of Children's Motrin® Bubble Gum Flavor

For Ages 2 to 11

PAIN RELIEVER/FEVER REDUCER

Children's Ibuprofen Oral Suspension

100 mg per 5 mL (teaspoonful)

Pain Reliever / Fever Reducer (NSAID)

Alcohol Free

Gluten Free

Lasts up to 8 HOURS

**Bubble Gum Flavor** 



For Ages 2 to 11

PAIN RELIEVER/

## Children's Ibuprofen Oral Suspension

100 mg per 5 mL (teaspoonful) Pain Reliever/Fever Reducer (NSAID)

NDC 49738-166-26

Compare to the active ingredient of Children's Motrin® Bubble Gum Flavor\*\*



For Ages 2 to 11

PAIN RELIEVER/ FEVER REDUCER

# Children's Ibuprofen **Oral Suspension**

100 mg per 5 mL (teaspoonful)

Pain Reliever/ Fever Reducer (NSAID)

Alcohol Free Gluten Free



Lasts up to 8 HOURS **Bubble Gum** Flavor

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children.

### Drug Facts

Active ingredient Purposes (in each 5 mL = 1 teaspoonful)

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nonsteroidal anti-inflammatory drug

### Uses temporarily:

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- right before or after heart surgery

### Ask a doctor before use if

- stomach bleeding warning applies to
- child has a history of stomach problems. such as heartburn





LOT NO.

EXP.

: 16626 FT C4





### Drug Facts (continued)

- child has problems or serious side effects from taking pain relievers or fever reducers
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### Drug Facts (continued)

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## Questions or comments?

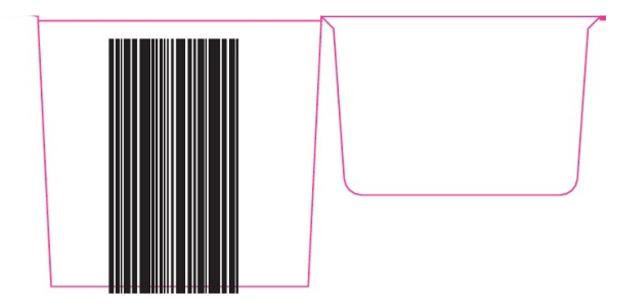
\*\*This product is not manufactured or distributed by McNell Consumer Healthcare, distributor of Children's Motrin® Bubble Gum Flavor.

Distributed by: Kmart Corporation Hoffman Estates, IL 60179 **Shop kmart.com** 

### SATISFACTION GUARANTEE



Thank you for purchasing this quality product. If you are unsatisfied for any reason, return the unused portion to the store for a full refund or call 1-800-842-7886.



### **SMART SENSE IBUPROFEN**

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:49738-166
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPROFEN (IBUPROFEN)	IBUPROFEN	100 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID			
FD&C RED NO. 40			
GLYCERIN			
HIGH FRUCTOSE CORN SYRUP			
HYPROMELLOSES			
POLYSORBATE 80			
WATER			
SO DIUM BENZO ATE			
SORBITOL			
XANTHAN GUM			

Product Characteristics			
Color	PINK (light)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-166-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		
2	NDC:49738-166-34	1 in 1 CARTON		
2		237 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074937	05/20/2010	

## Labeler - Kmart Corporation (008965873)

Revised: 1/2014 Kmart Corporation