

**IBUPROFEN CHILDRENS- ibuprofen suspension**  
**Best Choice (Valu Merchandisers Company)**

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**Ibuprofen Oral Suspension, USP**

***Drug Facts***

***Active ingredient***

***(in each 5 mL)***

Ibuprofen, USP 100 mg (NSAID)\*\*

\*\*nonsteroidal anti-inflammatory drug

***Purpose***

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

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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 ibuprofen or 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, kidney disease, or had a stroke
- 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**

- take with food or milk if stomach upset occurs

### **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
- child has symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- 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
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- 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

### Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	11 years	15 mL

\*or as directed by a doctor

### Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20° to 25°C (68° to 77°F)
- **do not use if printed neckband is broken or missing**
- see bottom panel for lot number and expiration date

### Inactive ingredients

**Grape:** acesulfame potassium, artificial grape flavor, citric acid anhydrous, D&C red #33, FD&C blue #1, FD&C red #40, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, sucrose, xanthan gum

**Original Berry:** acesulfame potassium, citric acid anhydrous, D&C yellow #10, FD&C red #40, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, strawberry flavor, sucrose, xanthan gum

**Dye-Free Berry:** acesulfame potassium, citric acid anhydrous, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, strawberry flavor, sucrose, xanthan gum

**Questions? 1-800-432-8534 between 9 am and 4 pm, EST Monday–Friday.**

### PRINCIPAL DISPLAY PANEL

For Ages 2 to 11 years

Best Choice®

### See New Warnings

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTRIN® GRAPE†

Children's Ibuprofen Oral Suspension, USP  
(NSAID)

100 mg per 5 mL

- Pain Reliever
- Fever Reducer
- Lasts up to 8 hours

# GRAPE FLAVOR

Shake Well  
Before Using

Alcohol Free

4 FL OZ (118 mL)

**Best Choice**

## Children's Ibuprofen

Oral Suspension, USP (NSAID)  
100 mg per 5 mL

For Ages 2 to 11 years

**Best Choice**

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTRIN® GRAPE

## Children's Ibuprofen

Oral Suspension, USP (NSAID)  
100 mg per 5 mL

• Pain Reliever  
• Fever Reducer  
• Lasts up to 8 hours

GRAPE FLAVOR  
Shake Well  
Before Using

Alcohol Free  
4 FL OZ (118 mL)

**Drug Facts (continued)**

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, kidney disease, or had a stroke
- 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**

- take with food or milk if stomach upset occurs
- 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
- child has symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- 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

\*This product is not affiliated with, manufactured by, or produced by the makers or owners of Children's Motrin®. 17620317 GW710096 R0417

**Drug Facts (continued)**

mL = milliliter

- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- 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

Dosing Chart		
Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-85 lbs	11 years	15 mL

\*or as directed by a doctor

**Other information**

- each 5 mL contains sodium 2 mg
- store between 20° to 25°C (68° to 77°F)
- do not use if printed neckband is broken or missing
- see bottom panel for lot number and expiration date

**Inactive ingredients:** acesulfame potassium, artificial grape flavor, citric acid anhydrous, D&C red #33, FD&C blue #1, FD&C red #40, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, sucrose, xanthan gum

**Questions? 1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.**  
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BEST CHOICE

0 70038 59738 4

## PRINCIPAL DISPLAY PANEL

For Ages 2 to 11 years

Best Choice®

See New Warnings

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTRIN® BERRY†

Children's Ibuprofen Oral Suspension, USP  
(NSAID)

100 mg per 5 mL

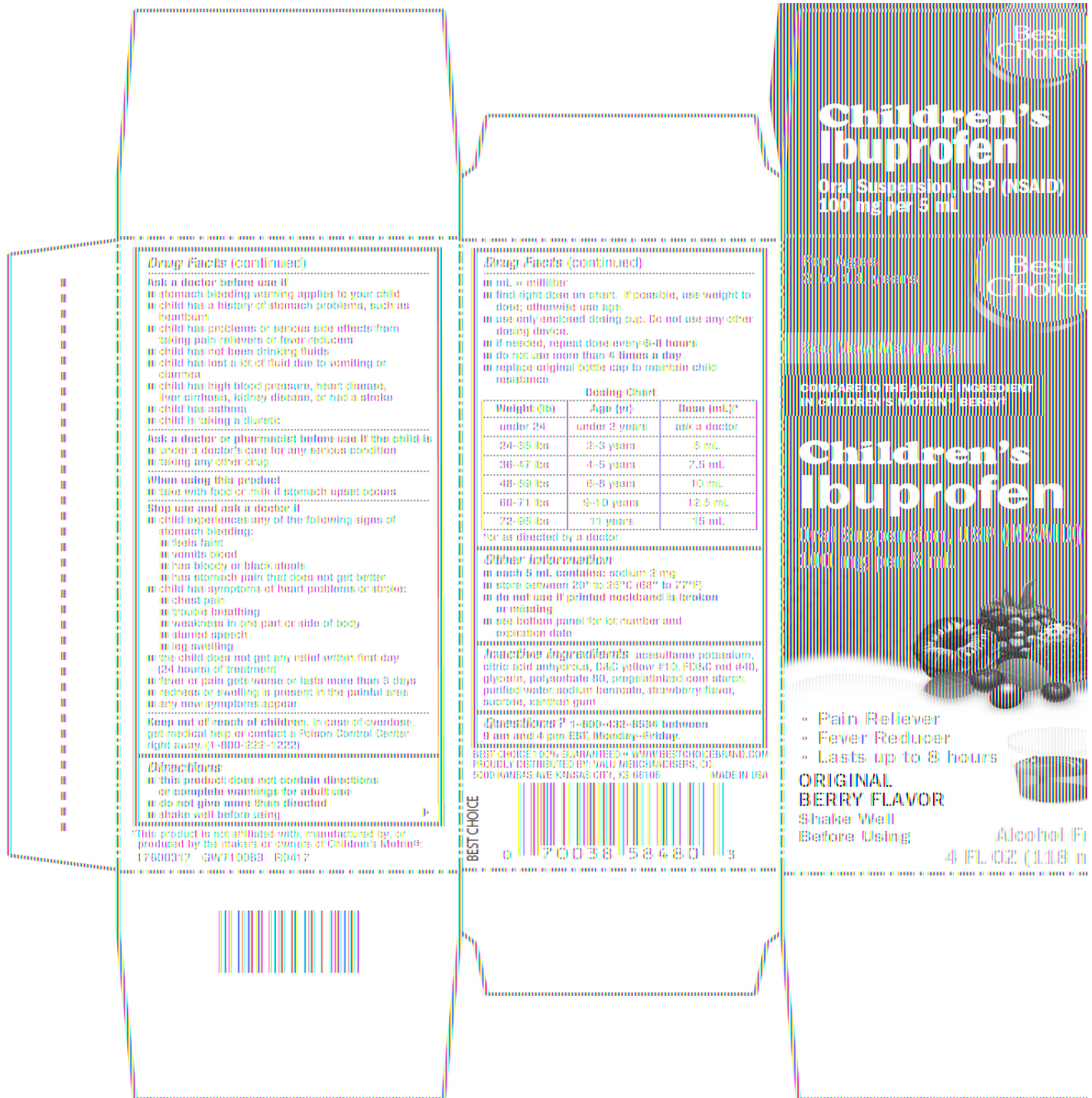
- Pain Reliever
- Fever Reducer
- Lasts up to 8 hours

ORIGINAL BERRY FLAVOR

Shake Well  
Before Using

Alcohol Free

4 FL OZ (118 mL)



## PRINCIPAL DISPLAY PANEL

For Ages 2 to 11 years

Best Choice®

See New Warnings

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTRIN® DYE FREE BERRY†

Children's Ibuprofen Oral Suspension, USP  
(NSAID)  
100 mg per 5 mL

- Pain Reliever

- Fever Reducer
- Lasts up to 8 hours

NON-STAINING DYE-FREE  
BERRY FLAVOR

Shake Well  
Before Using

Alcohol Free

4 FL OZ (118 mL)

**Drug Facts (continued)**

**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, kidney disease, or had a stroke
- 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**

- take with food or milk if stomach upset occurs

**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
- child has symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- 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 rightaway. (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

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**Drug Facts (continued)**

- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- 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

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

\*or as directed by a doctor

**Other information**

- each 5 mL contains: sodium 2 mg
- store between 20° to 25°C (68° to 77°F)
- do not use if printed neckband is broken or missing
- see bottom panel for lot number and expiration date

**Inactive ingredients:** acesulfame potassium, citric acid anhydrous, glycerin, polyisorbate 80, pregelatinized corn starch, purified water, sodium benzoate, strawberry flavor, sucrose, xanthan gum

**Questions?** 1-800-432-8634, between 9 am and 4 pm EST, Monday-Friday.

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**Best Choice®**

## Children's Ibuprofen

**Oral Suspension, USP (NSAID)  
100 mg per 5 mL**

For ages 2 to 11 years

**Best Choice®**

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTRIN® DYE-FREE BERRY

## Children's Ibuprofen

Oral Suspension, USP (NSAID)  
100 mg per 5 mL

- Pain Reliever
- Fever Reducer
- Lasts up to 8 hours

**NON-STAINING DYE-FREE  
BERRY FLAVOR**

Shake Well  
Before Using

**Alcohol Fr**

**4 FL OZ (118 mL)**

BEST CHOICE

0 70038 63574 1

**IBUPROFEN CHILDRENS**

ibuprofen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63941-762
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-762-94	1 in 1 CARTON	12/26/2017	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA074916	12/26/2017	



# IBUPROFEN CHILDRENS

ibuprofen suspension

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-760
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	100 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-760-94	1 in 1 CARTON	01/25/2019	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074916	01/25/2019	

# IBUPROFEN CHILDRENS

ibuprofen suspension

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-761
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	100 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-761-94	1 in 1 CARTON	02/13/2019	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074916	02/13/2019	

**Labeler** - Best Choice (Valu Merchandisers Company) (868703513)

