IBUPROFEN CHILDRENS- ibuprofen suspension
Chain Drug Consortium, LLC

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 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 or 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
  - vomit 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 last 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 (1-800-222-1222) right away

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 5mL contains: sodium 2 mg
- store between 20º to 25ºC (68º to 77ºF)

Inactive ingredients

acesulfame potassium, citric acid anhydrous, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate,strawberry flavor, sucrose, xanthan gum

Inactive ingredients

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

Bubble Gum: acesulfame potassium, artificial bubble gum flavor, citric acid anhydrous,

FD&C red #40, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, 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

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

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

PRINCIPAL DISPLAY PANEL

See New Warnings

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

Premier Value®

For Ages 2 to 11 years
Children's Ibuprofen Oral Suspension, USP
(NSAID)
100 mg per 5 mL

- Pain Reliever
- Fever Reducer

Lasts up to 8 hours

Shake Well
Before Using

Original Berry Flavor

Alcohol Free

4 FL OZ (118 mL)

PRINCIPAL DISPLAY PANEL

See New Warnings

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

Premier Value®

For Ages 2 to 11 years
Children's Ibuprofen Oral Suspension, USP
(NSAID)
100 mg per 5 mL

- Pain Reliever
- Fever Reducer

Lasts up to 8 hours

Shake Well
Before Using

Bubble Gum Flavor

Alcohol Free

4 FL OZ (118 mL)

PRINCIPAL DISPLAY PANEL

See New Warnings

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

Premier Value®

For Ages 2 to 11 years
Children's Ibuprofen Oral Suspension, USP
(NSAID)
100 mg per 5 mL

- Pain Reliever
- Fever Reducer

Lasts up to 8 hours

Shake Well
Before Using

Grape Flavor

Alcohol Free

4 FL OZ (118 mL)

Principal display panel

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

For Ages 2 to 11 years

Children's Ibuprofen

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

- Pain Reliever
- Fever Reducer

Lasts up to 8 hours

Shake Well Before Using

Non-Staining

Dye-Free

Berry Flavor

Alcohol Free

FL OZ (mL)

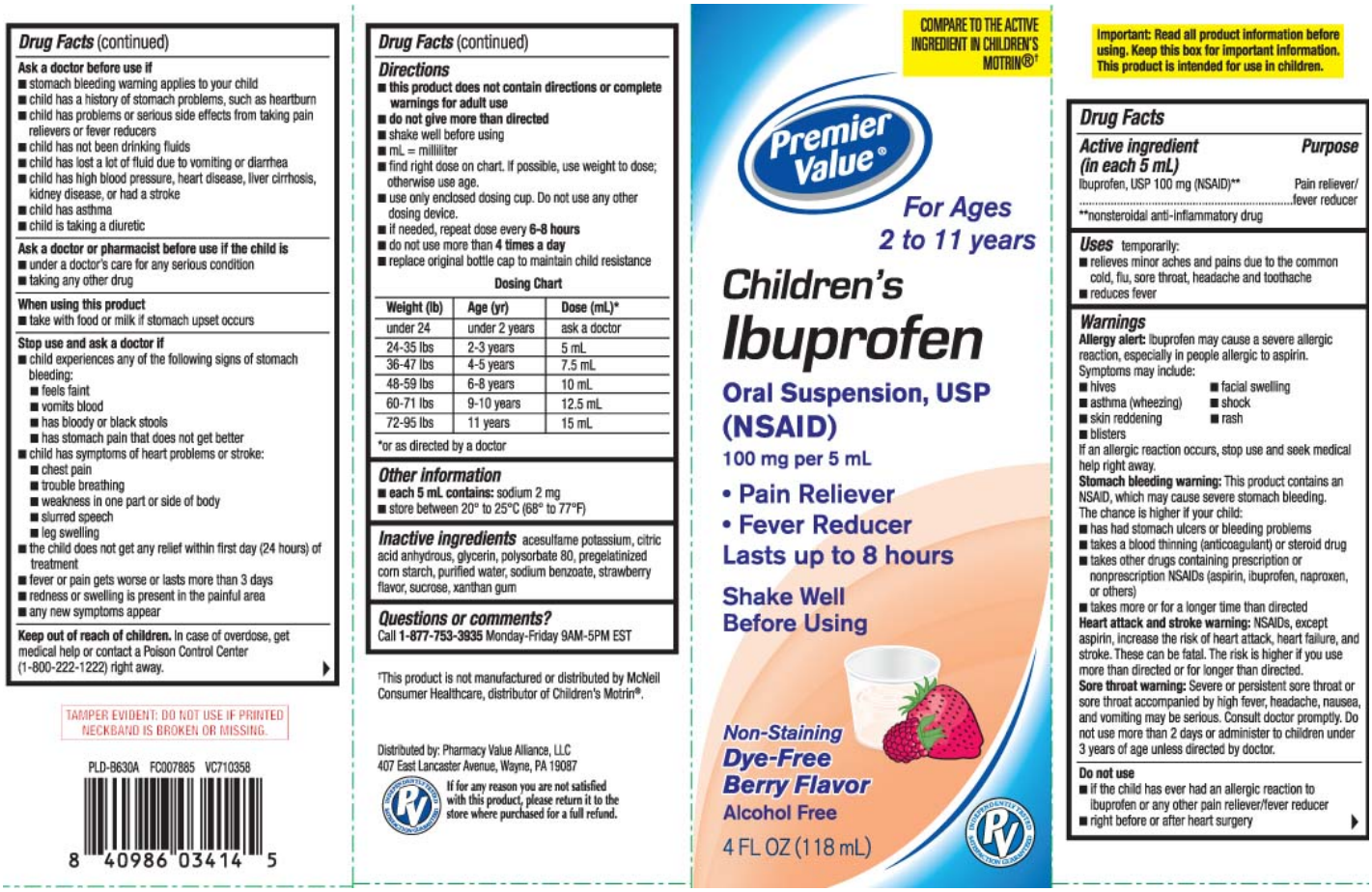
†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

TAMPER EVIDENT: DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

Distributed by: Pharmacy Value Alliance, LLC

407 East Lancaster Avenue, Wayne, PA 19087

Package label



PREMIER VALUE Children's Ibuprofen

IBUPROFEN CHILDRENS
ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-940
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	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: 059QF0KO0R)	
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:68016-940-08	1 in 1 CARTON	05/08/2018	
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68016-940-04	1 in 1 CARTON	09/26/2018	
2		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	05/08/2018	

IBUPROFEN CHILDRENS

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-942
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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)	

Product Characteristics			
Color	pink	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68016-942-04	1 in 1 CARTON	07/17/2018	
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	07/17/2018	

IBUPROFEN CHILDRENS

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-943
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	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: 059QF0KO0R)	
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:68016-943-04	1 in 1 CARTON	09/27/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA074916	09/27/2018	

IBUPROFEN CHILDRENS

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-944
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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)	

Product Characteristics

Color	purple	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-944-04	1 in 1 CARTON	12/11/2018	
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	12/11/2018	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - P & L Development, LLC (079765031)

Revised: 11/2022 Chain Drug Consortium, LLC