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 20° to 25°C (68° to 77°F)

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) Children's *Ibuprofen* Oral Suspension, USP (NSAID) 100 mg per 5 mL See New Warnings Important: Read all product information before using. Keep this box for important information. This product is intended for use in children. Drug Facts (continued) Drug Facts (continued) COMPARE TO THE ACTIVE Ask a doctor before use if mL = milliliter INGREDIENT IN CHILDREN'S Motrin® Bubble Gum stomach bleeding warning applies to your child
child has a history of stomach problems, such as find right dose on chart. If possible, use weight to dose; otherwise use age.

use only enclosed dosing cup. Do not use any other Drug Facts Premier nearrourn

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 Active ingredient Purpose dosing device. ■ if needed, repeat dose every 6-8 hours Value (in each 5 mL) Pain reliever, fever reducer do not use more than 4 times a day
 replace original bottle cap to maintain child
 resistance buprofen, USP 100 mg (NSA/D)** "nonsteroidal anti-inflammatory drug diarmea ■ child has high blood pressure, heart disease, liver cirrhosis, kidney disease, or had a stroke For Ages Uses temporarily:
■ relieves minor aches and pains due to the commo cold, flu, sore throat, headache and toothache Dosing Chart 2 to 11 years child has asthma Weight (lb) Age (yr) Dose (mL)* child is taking a diuretic under 24 under 2 years ask a doctor Children's Ask a doctor or pharmacist before use if the child is under a doctor's care for any serious condition taking any other drug 24-35 lbs 2-3 years 5 mL Warnings
Allergy alert: buprofen may cause a severe
allergic reaction, especially in people allergic to 36-47 lbs 4-5 years 7.5 ml *lbuprofen* When using this product 48-59 lbs 6-8 years 10 mL take with food or milk if stomach upset occurs aspirin. Symptoms may include: aspirin, Symptoms may include:

I hives

asthma (wheezing)

siden reddening

rash

blisters

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

Stomach bleeding warming: This product contains
an NSAD, which may cause servers stomach
bleeding. The choose is blished if the use hills. 60-71 lbs 9-10 years 12.5 mL Stop use and ask a doctor if
child experiences any of the following signs of stomach bleeding:
feels faint Oral Suspension, USP 72-95 lbs 11 years 15 mL or as directed by a doctor (NSAID) ■ vomits blood Other information 100 mg per 5 mL m has bloody or black stools 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 has stomach pain that does not get better
 child has symptoms of heart problems or stroke; Pain Reliever bleeding. The chance is higher if your child:

• has had stomach ulcers or bleeding proble

• takes a blood thinning (anticoagulant) or ■ chest pain
■ chest pain
■ trouble breathing
■ weakness in one part or side of body Fever Reducer or missing see bottom panel for lot number and takes a blood minning (annicoagulant) or steroid drug
 takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, Lasts up to 8 hours expiration date ■ leg swelling Inactive ingredients accountame potassium artificial bubble gum flavor, citric acid anhydrous, FD&C red #40, glycerin, polysorbate 80, the child does not get any relief within first day (24 hours) of treatment Shake Well naproxen, or others) naproxen, or others)

**Bakes more or for a longer time than directed

**Heart attack and stroke warning: NSAIDs, except

**applin, increase the risk of heart attack, heart failure,

and stroke. These can be fast. The risk is higher if you

use more than directed or for longer than directed. fewer or pain gets worse or lasts more than 3 days
 rechess or swelling is present in the painful area
 any new symptoms appear **Before Using** pregelatinized corn starch, purified water, sodium zoate, sucrose, xanthan gum 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) Questions? 1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday. Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, Distributed by: Pharmacy Value Alliance, LLC 407 East Lancaster Avenue, Wayne, PA 19087 breadache, nausea, and vomitting 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. Directions this product does not contain directions or complete warnings for adult use do not give more than directed shake well before using **Bubble Gum Flavor**

Alcohol Free

4 FL OZ (118 mL)

if the child has ever had an allergic reaction to

ibuprofen or any other pain reliever/fever reducer

right before or after heart surgery

(R)

PRINCIPAL DISPLAY PANEL See New Warnings

This product is not affiliated with, manufactured by, or

produced by the makers or owners of Children's Motrin® Made in USA 17630317 GW710158 R0417

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)

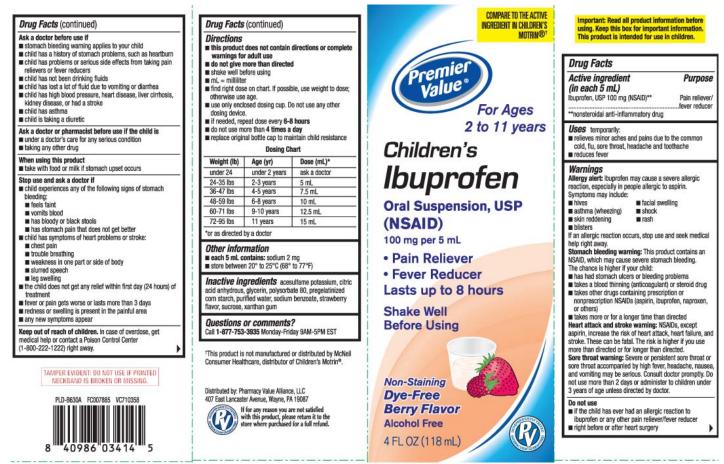
†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

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: 230V73Q5G9)		
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: 60ZP39ZG8H)		
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				

P	Packaging Packag					
#	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 Application Number or Monograph Marketing Start Marketing End Category Citation Date 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 IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) Basis of Strength 100 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
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			

F	Packaging				
#	tem 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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM) | IBUPROFEN | 100 mg in 5 mL

Strength

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	

SODIUM BENZOATE (UNII: OJ245FE5EU)
SUCROSE (UNII: C151H8M554)

XANTHAN GUM (UNII: TTV12P4NEE)

Product Characteristics

1 Todact Characteristics			
Color	white	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

	. ackaging			
#	tem 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 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: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
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)	

Product Characteristics

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

	Color	purple	Score	
	Shape		Size	
	Flavor	GRAPE	Imprint Code	
- 1				

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