### IBUPROFEN CHILDRENS- ibuprofen suspension QUALITY CHOICE (Chain Drug Marketing Association)

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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
- $\blacksquare$  asthma (wheezing)  $\blacksquare$  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

**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)

# Direction

• 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

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

# **Dosing Chart**

# 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

**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

# Questions? 1-888-838-2872 between 9 am and 5 pm ET, Monday-Friday.

# PRINCIPAL DISPLAY PANEL

QC<sup>®</sup> QUALITY CHOICE

NDC 63868-776-04

<sup>†</sup>Compare to the active ingredient in CHILDREN'S MOTRIN<sup>®</sup> GRAPE

### See New Warnings

For Ages 2 to 11 years

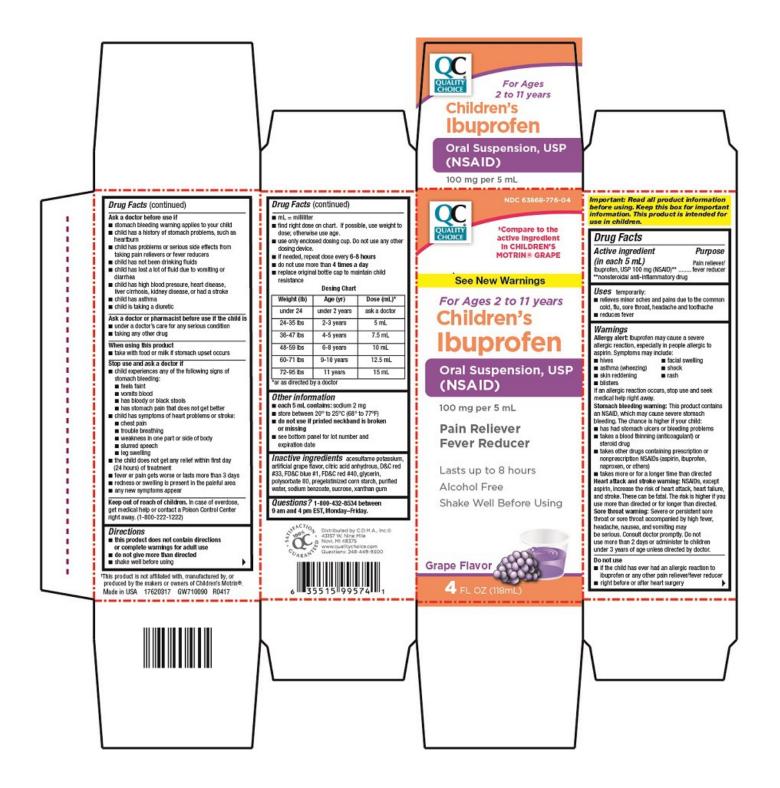
Children's Ibuprofen Oral Suspension, USP (NSAID) 100 mg per 5 mL

Pain Reliever Fever Reducer

Lasts up to 8 hours Alcohol Free Shake Well Before Using

Grape Flavor

4 FL OZ (118mL)



# PRINCIPAL DISPLAY PANEL

QC<sup>®</sup> QUALITY CHOICE

NDC 63868-779-04

<sup>†</sup>Compare to the active ingredient in CHILDREN'S MOTRIN<sup>®</sup> BERRY

### See New Warnings

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 Alcohol Free Shake Well Before Using

Original Berry Flavor

4 FL OZ (118mL)



### PRINCIPAL DISPLAY PANEL

QC<sup>®</sup> QUALITY CHOICE

NDC 63868-724-04

<sup>†</sup>Compare to the Active Ingredient in Children's Motrin<sup>®</sup> Dye-Free Berry

### See New Warnings

For Ages 2 to 11 years

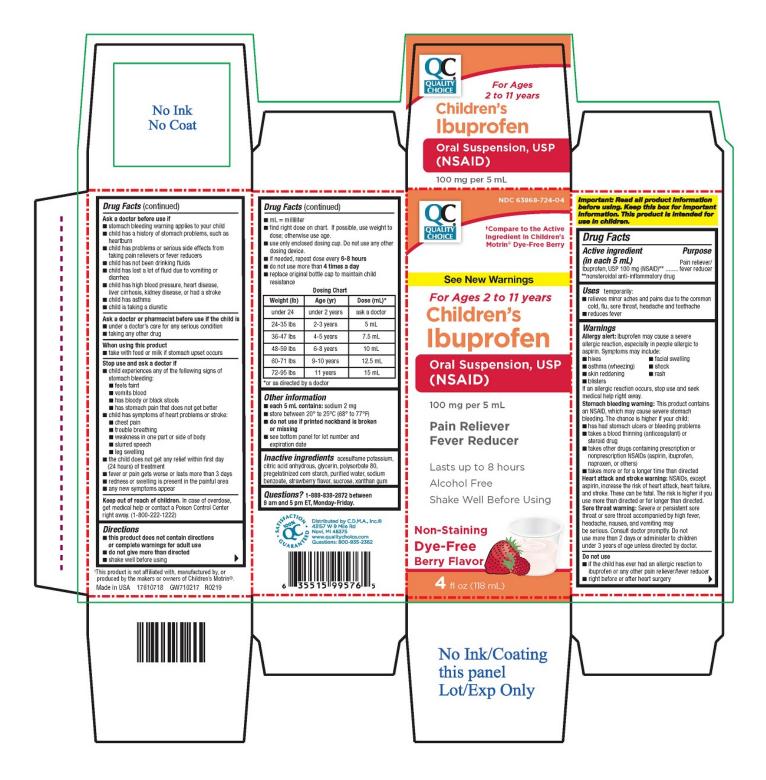
Children's Ibuprofen Oral Suspension, USP **(NSAID)** 100 mg per 5 mL

Pain Reliever Fever Reducer

Lasts up to 8 hours Alcohol Free Shake Well Before Using

Non-Staining Dye-Free Berry Flavor

4 fl oz (118 mL)



### PRINCIPAL DISPLAY PANEL

QC<sup>®</sup> QUALITY CHOICE

NDC 63868-709-04

<sup>†</sup>Compare to the Active Ingredient in Children's Motrin<sup>®</sup> Bubble Gum

### See New Warnings

For Ages 2 to 11 years

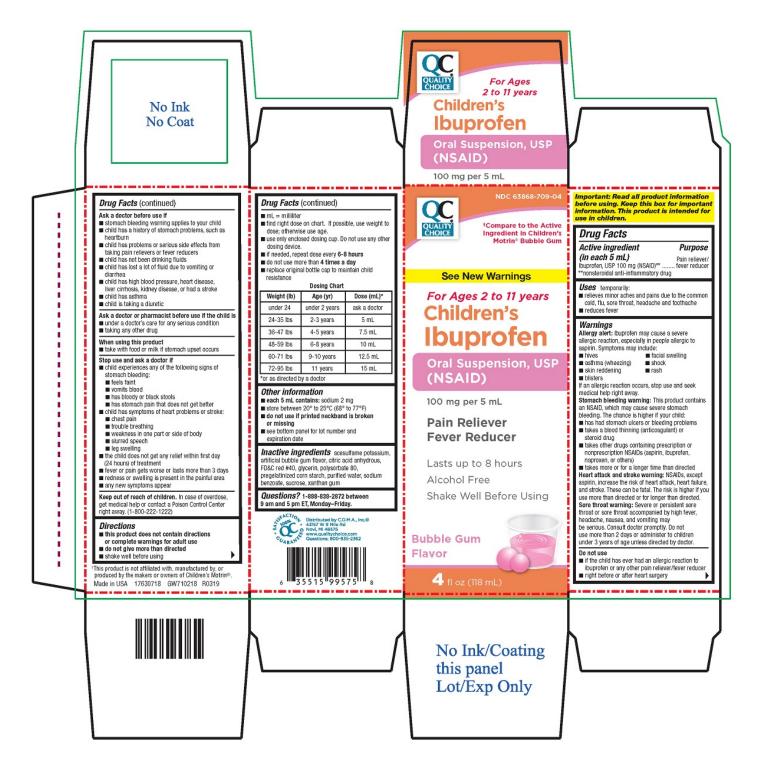
Children's Ibuprofen Oral Suspension, USP **(NSAID)** 100 mg per 5 mL

Pain Reliever Fever Reducer

Lasts up to 8 hours Alcohol Free Shake Well Before Using

Bubble Gum Flavor

4 fl oz (118 mL)



<b>IBUPROFEN CHILDR</b> ibuprofen suspension	ENS		
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-776
Route of Administration	ORAL		
Active Ingredient/Active	Moiety		
Ingredi	ent Name	Basis of Strengt	th Strength

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM)	IBUPROFEN
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Inactive Ingre	diants				
mactive ingre	uents	Ingredient Nam	۵		Strength
ACESULFAME POT	ASSIUM (UNII)				Stiength
ANHYDROUS CITR					
FD&C RED NO. 40					
GLYCERIN (UNII: PI		- ,			
POLYSORBATE 80		2G8H)			
STARCH, CORN (U					
WATER (UNII: 0590	F0KO0R)				
SODIUM BENZOA	<b>FE</b> (UNII: OJ245F	E5EU)			
SUCROSE (UNII: C1	51H8M554)				
XANTHAN GUM (U	NII: TTV12P4NEE	)			
D&C RED NO. 33	UNII: 9DBA0SBE	30L)			
FD&C BLUE NO. 1	(UNII: H3R47K3	TBD)			
Product Char	acteristics				
Color		purple	Score		
Shape			Size		
Flavor		GRAPE	Imprint Co	ode	
Contains					
contains					
Packaging					
# Item Code	Pa	ckage Descriptio	n	Marketing Start Date	Marketing End Date
<b>1</b> NDC:63868-776-	1 in 1 CARTON			03/22/2018	
1	118 mL in 1 BC Product	OTTLE; Type 0: Not a C	Combination		
Marketing	Informat	ion			
Marketing Marketing Category		<b>ion</b> tion Number or Mo Citation	onograph	Marketing Start Date	Marketing End Date

# **IBUPROFEN CHILDRENS**

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-779
Route of Administration	ORAL		

	ient/Acti			<b>D</b> · ( <b>C</b> )	
	-	edient Name	0/110000	Basis of Streng	-
BUPROFEN (UNII:	WKZXYIIUQ	M) (IBUPROFEN - UNII:WK2)	(YILUQM)	IBUPROFEN	100 mg in 5 ml
Inactive Ingre	dients				
		Ingredient Nam	е		Strength
ACESULFAME POT	TASSIUM (I	JNII: 230V73Q5G9)			
ANHYDROUS CITR					
D&C YELLOW NO.					
FD&C RED NO. 40					
GLYCERIN (UNII: PI					
POLYSORBATE 80 STARCH, CORN (U	•	· ·			
WATER (UNII: 0590		(155 <u>)</u>			
SODIUM BENZOAT		245FE5EU)			
SUCROSE (UNII: C1					
XANTHAN GUM (UI					
Product Chara	acteristi				
		CS			
		orange	Sc	ore	
Color			Sc		
Color Shape			Si		
Color Shape Flavor		orange	Si	ze	
Color Shape Flavor Contains		orange	Si	ze	
Color Shape Flavor Contains		orange	Si	ze print Code	
Color Shape Flavor Contains <b>Packaging</b>		orange	Si	ze	Marketing End Date
Color Shape Flavor Contains Packaging # Item Code	1 in 1 CAR	orange STRAWBERRY Package Descriptio	Si	ze print Code Marketing Start	
Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-779- 08	1 in 1 CAR	orange STRAWBERRY Package Descriptio	n	ze print Code Marketing Start Date	
Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-779- 08	1 in 1 CAR 237 mL in	orange STRAWBERRY Package Descriptio TON 1 BOTTLE; Type 0: Not a C	n	ze print Code Marketing Start Date	
Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-779- 08 2 NDC:63868-779- 04	1 in 1 CAR 237 mL in Product 1 in 1 CAR	orange STRAWBERRY Package Descriptio TON 1 BOTTLE; Type 0: Not a C	n Combination	ze print Code Marketing Start Date 03/22/2018	
Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-779- 08 2 NDC:63868-779-	1 in 1 CAR 237 mL in Product 1 in 1 CAR 118 mL in	orange STRAWBERRY Package Descriptio TON 1 BOTTLE; Type 0: Not a C TON	n Combination	ze print Code Marketing Start Date 03/22/2018	
Color Shape Flavor Contains PCKaging Item Code 1 NDC:63868-779- 08 2 NDC:63868-779- 2 NDC:63868-779-	1 in 1 CAR 237 mL in Product 1 in 1 CAR 118 mL in Product	orange STRAWBERRY Package Descriptio TON 1 BOTTLE; Type 0: Not a C TON 1 BOTTLE; Type 0: Not a C	n Combination	ze print Code Marketing Start Date 03/22/2018	
Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-779- 08 2 NDC:63868-779-	1 in 1 CAR 237 mL in Product 1 in 1 CAR 118 mL in Product	orange STRAWBERRY Package Descriptio TON 1 BOTTLE; Type 0: Not a C TON 1 BOTTLE; Type 0: Not a C	n Combination	ze print Code Marketing Start Date 03/22/2018	

# **IBUPROFEN CHILDRENS**

ibuprofen suspension

Product Infor Product Type	mation				
Product Type					
		HUMAN OTC DRUG	Item C	ode (Source)	NDC:63868-724
Route of Admini	stration	ORAL			
Active Ingredi	ent/Acti	ve Moiety			
		edient Name		Basis of Streng	th Strength
BUPROFEN (UNII:	-	M) (IBUPROFEN - UNII:WK2XYI10	QM)	IBUPROFEN	100 mg in 5 mL
Inactive Ingre	dients				
		Ingredient Name			Strength
ACESULFAME POT					
ANHYDROUS CITR	IC ACID (U	NII: XF417D3PSL)			
GLYCERIN (UNII: PE					
POLYSORBATE 80					
STARCH, CORN (U	NII: 08232N	IY3SJ)			
WATER (UNII: 059Q	F0KO0R)				
SODIUM BENZOAT	E (UNII: OJ	245FE5EU)			
SUCROSE (UNII: C1	51H8M554)				
Product Chara	acteristi	cs			
Color		white	Sco	ore	
Shape			Siz	e	
Flavor		STRAWBERRY	Imp	orint Code	
Contains			•		
Packaging					
# Item Code		Package Description		Marketing Start Date	Marketing End Date
<b>1</b> NDC:63868-724- 04	1 in 1 CAR	ΤΟΝ		03/09/2020	
1	118 mL in Product	1 BOTTLE; Type 0: Not a Comb	bination		
Marketing	Inform	ation			
Marketing Marketing Category		I <b>ation</b> lication Number or Monog Citation	graph	Marketing Start Date	Marketing End Date

# **IBUPROFEN CHILDRENS**

ibuprofen suspension

	mation				
Product Type		HUMAN OTC DRUG	ltem Co	de (Source)	NDC:63868-709
Route of Admin	istration	ORAL			
Active Ingred	ient/Act	ive Moiety			
	Ingr	redient Name		Basis of Streng	th Strength
BUPROFEN (UNII:	WK2XYI10Q	M) (IBUPROFEN - UNII:WK2XYI1)	0QM)	IBUPROFEN	100 mg in 5 mL
nactive Ingre	dients				
		Ingredient Name			Strength
ACESULFAME POT		UNII: 230V73Q5G9)			
ANHYDROUS CITR	IC ACID (U	INII: XF417D3PSL)			
FD&C RED NO. 40	(UNII: WZ E	39127XOA)			
GLYCERIN (UNII: PI	DC6A3C00>	<)			
POLYSORBATE 80	(UNII: 60Z	(P39ZG8H)			
STARCH, CORN (U	NII: 082321	NY3SJ)			
WATER (UNII: 059C	F0KO0R)				
SODIUM BENZOA		245FE5EU)			
SUCROSE (UNII: C1	51H8M554	)			
SUCROSE (UNII: C1	51H8M554	)			
SUCROSE (UNII: C1 XANTHAN GUM (UI	.51H8M554 NII: TTV12P	) 4NEE)			
SUCROSE (UNII: CI XANTHAN GUM (UI Product Chara	.51H8M554 NII: TTV12P	) 4NEE) ics			
SUCROSE (UNII: CI XANTHAN GUM (UI Product Chara Color	.51H8M554 NII: TTV12P	) 4NEE)	Scor	e	
SUCROSE (UNII: C1 XANTHAN GUM (UI Product Chara Color Shape	.51H8M554 NII: TTV12P	) 4NEE) i <b>CS</b> pink	Size		
SUCROSE (UNII: C1 XANTHAN GUM (UI Product Chara Color Shape	.51H8M554 NII: TTV12P	) 4NEE) ics	Size	e int Code	
SUCROSE (UNII: CI XANTHAN GUM (UI Product Chara Color Shape Flavor	.51H8M554 NII: TTV12P	) 4NEE) i <b>CS</b> pink	Size		
SUCROSE (UNII: CI XANTHAN GUM (UI Product Chara Color Shape Flavor	.51H8M554 NII: TTV12P	) 4NEE) i <b>CS</b> pink	Size		
SUCROSE (UNII: CI XANTHAN GUM (UI Product Chara Color Shape Flavor Contains	.51H8M554 NII: TTV12P	) 4NEE) i <b>CS</b> pink	Size Impr	int Code	
SUCROSE (UNII: CI XANTHAN GUM (UI Product Chara Color Shape Flavor Contains Packaging	.51H8M554 NII: TTV12P	) 4NEE) i <b>CS</b> pink	Size Impr		Marketing End Date
SUCROSE (UNII: CI XANTHAN GUM (UN Product Chara Color Shape Flavor Contains Packaging # Item Code	51H8M554 NII: TTV12P <b>acterist</b> 1 in 1 CAR	) 4NEE) ics pink BUBBLE GUM Package Description	Size Impr	int Code Marketing Start	
SUCROSE (UNII: C1 XANTHAN GUM (UI Product Chara Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-709- 04	51H8M554 NII: TTV12P <b>acterist</b> 1 in 1 CAR	) 4NEE) ics pink BUBBLE GUM Package Description	Size Impr	int Code Marketing Start Date	
SUCROSE (UNII: C1 KANTHAN GUM (UI Product Chara Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-709- 04	1 in 1 CAR Product	) 4NEE) ics pink BUBBLE GUM Package Description TON 1 BOTTLE; Type 0: Not a Com	Size Impr	int Code Marketing Start Date	
SUCROSE (UNII: C1 XANTHAN GUM (UI Product Chara Color Shape Flavor Contains Packaging # Item Code 1 NDC:63868-709- 04	1 in 1 CAR Product	) 4NEE) ics pink BUBBLE GUM Package Description TON 1 BOTTLE; Type 0: Not a Com	Size Impr	int Code Marketing Start Date	
1 NDC:63868-709-	51H8M554 NII: TTV12P Acteristi Acteristi 1 in 1 CAR 118 mL in Product	) 4NEE) ics pink BUBBLE GUM Package Description TON 1 BOTTLE; Type 0: Not a Com	Size Impr bination	int Code Marketing Start Date	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 10/2023

QUALITY CHOICE (Chain Drug Marketing Association)