

**CHILDRENS MOTRIN- ibuprofen suspension**  
**Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division**

-----  
**Children's Motrin**

***Drug Facts***

**Active ingredient (in each 5 mL)**

Ibuprofen 100 mg (NSAID)<sup>1</sup>

---

<sup>1</sup> 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 20-25°C (68-77°F)
- **do not use if carton is opened or if carton tape or bottle wrap imprinted "SAFETY SEAL®" is broken or missing**

### Inactive ingredients

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

### Questions or comments?

Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

### PRINCIPAL DISPLAY PANEL

*See New Warnings*

NDC 50580-184-50

*For Ages 2 to 11 Years*

*Children's  
Motrin®*

*contains Ibuprofen  
Oral Suspension (NSAID)  
100 mg per 5 mL*

*Pain Reliever / Fever Reducer*

*DYE - FREE*

*Lasts up to  
8 hours*

***Alcohol Free***

***Non-Staining***

***Original Berry Flavor***

**4 fl oz (120 mL)**

# Children's Motrin<sup>®</sup>

**DYE - FREE**

contains  
**Ibuprofen Oral Suspension (NSAID)**

Non-Staining  
**Original Berry Flavor**

See New Warnings

NDC 50580-184-50

For Ages 2 to 11 Years

# Children's Motrin<sup>®</sup>

contains **Ibuprofen**  
**Oral Suspension (NSAID)**  
100 mg per 5 mL

**Pain Reliever / Fever Reducer**

**DYE - FREE**

Lasts up to  
**8 hours**

**Alcohol Free**



**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 (in each 5 mL)	Purpose
Ibuprofen 100 mg (NSAID)*	Pain reliever/ fever reducer

\*nonsteroidal anti-inflammatory drug

## 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.

INSIDE VARNISH  
FREE VARNISH

**Non-Staining  
Original Berry Flavor**

**4 fl oz (120 mL)**



3 0045-0184-047



...respirators, fevers, 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



**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

**Drug Facts (continued)**

- 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

- 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. →

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 20-25°C (68-77°F)
- do not use if carton is opened or if carton tape or bottle wrap imprinted "SAFETY SEAL®" is broken or missing

**Inactive ingredients** acesulfame potassium, anhydrous citric acid, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

**Questions or comments?**

Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Distributed by:

**JOHNSON & JOHNSON CONSUMER INC.**

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA

©J&JCI 2017

[www.motrin.com](http://www.motrin.com)

30038105

**CHILDRENS MOTRIN**

ibuprofen suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-184
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>acesulfame potassium</b> (UNII: 23OV73Q5G9)	
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>water</b> (UNII: 059QF0K00R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	WHITE (Off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-184-50	1 in 1 CARTON	02/28/2012	
1		120 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		
2	NDC:50580-184-51	2 in 1 PACKAGE	02/04/2019	
2		1 in 1 CARTON		
2		120 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA020516	09/01/2001	



Revised: 6/2019

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division