# IBUPROFEN CHILDRENS- ibuprofen suspension Walgreen Company

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#### Walgreen Co. Ibuprofen 100 Drug Facts

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

Ibuprofen 100 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

#### **Purposes**

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

• give 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
- wash dosage cup after each use

#### **Dosing Chart**

Weight (lb)	Age (yr)	Dose (mL)**
under 24 lbs	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

<sup>\*\*</sup>or as directed by a doctor

#### Other information

- each 5 mL contains: sodium 2 mg
- do not use if printed neckband is broken or missing
- store at  $20-25^{\circ}$ C (68-77°F)
- do not freeze

#### **Inactive ingredients**

anhydrous citric acid, artificial mixed berry flavor, D&C yellow #10, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

#### Questions or comments?

1-800-719-9260

#### **Principal Display Panel**

Compare to Children's Motrin® active ingredient

children's

Ibuprofen 100

IBUPROFEN ORAL SUSPENSION 100 mg PER 5 mL

PAIN RELIEVER / FEVER REDUCER (NSAID)

LASTS UP TO 8 HOURS

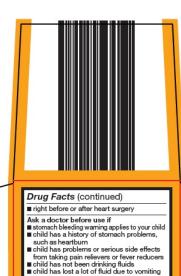
ALCOHOL FREE

AGES 2 TO 11 YEARS

4 FL OZ (118 mL)

**BERRY FLAVOR** 

SEE NEW WARNINGS



■ 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

■ taking any other drug

stroke: ■ chest pain

■ under a doctor's care for any serious condition

When using this product ■ give 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:

or 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

trouble breathing
 weakness in one part or side of body
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 leg swelling
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Questions or comments?



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## Walgreens

PAIN RELIEVER / FEVER REDUCER (NSAID)

Walgreens

children's

**Ibuprofen** 

IBUPROFEN ORAL SUSPENSION 100 mg PER 5 mL

Compare to Children's Motrin® active ingredient#

children's

# **Ibuprofen** 100

**IBUPROFEN** ORAL SUSPENSION 100 mg PER 5 mL PAIN RELIEVER / FEVER REDUCER (NSAID)

LASTS UP TO 8 HOURS

ALCOHOL FREE





SEE NEW WARNINGS

### PORTANT: READ ALL PRODUCT INFORMATION BEFORE

Drug Facts

Active ingredient (in each 5 mL) Purposes

Ibuprofen 100 mg (NSAID)\*. .Pain reliever/ \*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
- 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
- has had stomach ulcers or bleeding problems ■ takes a blood thinning (anticoagulant) or
- steroid drug

  takes other drugs containing prescription
- takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

  It takes more or for a longer time than directed Heart attack and stroke warring; 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 warring: 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





89726 94 C16



## IBUPROFEN CHILDRENS

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0897
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		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)			
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SORBITOL (UNII: 506T60A25R)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Product Characteristics			
Color	ORANGE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0363-0897-26	1 in 1 CARTON	03/11/1999	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0897-34	1 in 1 CARTON	01/29/2008	
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-0897-28	1 in 1 CARTON	09/28/2013	
3		148 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	ANDA074937	03/11/1999	

## Labeler - Walgreen Company (008965063)

Revised: 2/2020 Walgreen Company