IBUPROFEN CHILDRENS- ibuprofen suspension Walgreen Company

Walgreen Co. Children's 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, or 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 of 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	

^{**} 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°C (68-77°F)
- do not freeze

Inactive ingredients

anhydrous citric acid, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredient in Children's Motrin®

Children's Ibuprofen 100

IBUPROFEN ORAL SUSPENSION 100 mg PER 5 mL

PAIN RELIEVER / FEVER REDUCER (NSAID)

Lasts Up To 8 Hours

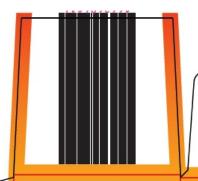
Alcohol Free

AGES 2 TO 11 YEARS

4 FL OZ (118 mL)

Bubble Gum flavor

SEE NEW WARNINGS





Children's **Ibuprofen** 100

Drug Facts (continued)

■ right before or after heart surgery

Ask a doctor before use if

- Ask a doctor before use if

 stomach bleeding warring 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 distrate.
- 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

- I child has symptoms or neart problems of stroke:

 It chest pain

 I trouble breathing

 weakness in one part or side of body

 Juned speech

 Lo awailing
- leg swelling
 the child does not get any relief within first day (24 hours) of treatment or pain gets worse or lasts more than
- a 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 Poiso Control Center right away. (1-800-222-1222)

Directions

this product does not contain direct or complete warnings for adult use do not give more than directed

Drug Facts (continued)

- 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

Doning 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	

- Other information

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

Inactive ingredients anhydrous citric acid, FD&C red #40, glycerin, high fructose com syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

This product is not menufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Children's Motrin⁸.



DOSAGE CUP PROVIDED

NDC 0363-0166-26



Compare to the active ingredient in Children's Motrin'



Children's **Ibuprofen** 100

IBUPROFEN

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

Lasts Up To 8 Hours



SEE NEW WARNINGS

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING, KEEP THIS BOX FOR IMPORTANT INFORMATION.

Drug Facts

Active ingredient (in each 5 mL)

Purposes

| Ibuprofen 100 mg (NSAID)*......Pain reliever fever reduce *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

Allergy alert: Ibuprofen may cause a severe slergic reaction, especially in people allergic to aspirin. Symptoms may include:

■ hives
■ sthma (wheezing) ■ shock
■ skin reddening ■ rash
■ bisters
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:

- contrains an Naxau, which may cause several stomach bleeding. The chance is higher if your child:

 It has had stomach ulcers or bleeding problems

 It takes a blood thinning (anticoagulant) or steroid drug

 It takes other drugs containing prescription or nonprescription NaXADs (aspirin, ibuprofen, naproxen, or others)

 It takes more of 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, naussea, 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
- Do not use

 if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer







DISTRIBUTED BY: WAI GREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 100% SATISFACTION GUARANTEED walgreens.com @2021 Walgreen Co. ITEM 603681 W10106-0622-L



IBUPROFEN CHILDRENS

ibuprofen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0363-0166

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	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	PINK (light)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0166- 26	1 in 1 CARTON	03/04/2002	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0166- 28	1 in 1 CARTON	09/20/2013	12/31/2020
2		148 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-0166- 40	3 in 1 CARTON	03/04/2002	08/01/2017
3		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0363-0166- 34	2 in 1 CARTON	04/07/2008	02/18/2013
4		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	ANDA074937	03/04/2002	

Labeler - Walgreen Company (008965063)

Revised: 3/2023 Walgreen Company