

**GOOD NEIGHBOR PHARMACY IBUPROFEN- ibuprofen suspension**  
**Amerisource Bergen**

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**Amerisource Bergen Ibuprofen Oral Suspension Drug Facts**

**Active ingredient (in each 5 mL = 1 teaspoonful)**

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

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 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
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

### **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
- 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; tsp = teaspoonful
- 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 or tsp)** |
| under 24 lbs | under 2 years | ask a doctor       |
| 24-35 lbs    | 2-3 years     | 5 mL (1 tsp)       |
| 36-47 lbs    | 4-5 years     | 7.5 mL (1½ tsp)    |
| 48-59 lbs    | 6-8 years     | 10 mL (2 tsp)      |
| 60-71 lbs    | 9-10 years    | 12.5 mL (2½ tsp)   |
| 72-95 lbs    | 11 years      | 15 mL (3 tsp)      |

\*\*or as directed by a doctor

### Other information

- each 5 mL (1 tsp) 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
- see bottom panel for lot number and expiration date

### 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

FOR AGES 2 TO 11 YEARS

children's

Ibuprofen

Oral Suspension

100 mg per 5 mL

pain reliever/fever reducer (NSAID)

Lasts up to 8 hours

berry flavor

Alcohol Free

8 fl oz (240 mL)



| GOOD NEIGHBOR PHARMACY IBUPROFEN |                |                    |               |
|----------------------------------|----------------|--------------------|---------------|
| ibuprofen suspension             |                |                    |               |
| Product Information              |                |                    |               |
| Product Type                     | HUMAN OTC DRUG | Item Code (Source) | NDC:24385-905 |

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)    |          |
| GLYCERIN (UNII: PDC6A3C0OX)                 |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)            |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)           |          |
| WATER (UNII: 059QF0K00R)                    |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)          |          |
| SORBITOL (UNII: 506T60A25R)                 |          |
| XANTHAN GUM (UNII: TTV12P4NEE)              |          |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)        |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)          |          |

### Product Characteristics

|          |        |              |  |
|----------|--------|--------------|--|
| Color    | ORANGE | Score        |  |
| Shape    |        | Size         |  |
| Flavor   | BERRY  | Imprint Code |  |
| Contains |        |              |  |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:24385-905-34 | 1 in 1 CARTON   |                      |                    |
| 1 |                  | 240 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:24385-905-26 | 1 in 1 CARTON   |                      |                    |
| 2 |                  | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:24385-905-28 | 1 in 1 CARTON   |                      |                    |
| 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                               | 01/28/1999           |                    |

Labeler - Amerisource Bergen (007914906)

