

**JUNIOR STRENGTH ADVIL- ibuprofen tablet, coated**  
**Haleon US Holdings LLC**

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***Drug Facts***

***ACTIVE INGREDIENT (IN EACH TABLET)***

Ibuprofen 100 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

***PURPOSE***

Fever reducer/Pain reliever

***USES***

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

***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 the 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 any other pain reliever/fever reducer
- right before or after heart surgery

### **Ask a doctor before use if**

- stomach bleeding warning applies to the child
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has a history of stomach problems, such as heartburn
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- 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
- 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.

***DIRECTIONS***

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- repeat dose every **6-8 hours**, if needed
- do not use more than **4 times a day**

**Dosing Chart**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (tablets)</b>
under 48 lb	under 6 yr	ask a doctor
48-71 lb	6-10 yr	2 tablets
72-95 lb	11 yr	3 tablets

***OTHER INFORMATION***

- one dose lasts 6-8 hours
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- see side of box for lot number and expiration date

***INACTIVE INGREDIENTS***

acetylated monoglycerides, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze, pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, stearic acid, sucrose, synthetic iron oxides, titanium dioxide

***QUESTIONS OR COMMENTS?***

call toll free **1-800-88-ADVIL** or ask your pharmacist, doctor or health care professional



Ingredient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	100 mg	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SHELLAC (UNII: 46N107B71O)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCROSE (UNII: C151H8M554)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
Color	BROWN (tan)	Score	no score	
Shape	ROUND (round tablet)	Size	8mm	
Flavor		Imprint Code	Advil;100	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0175-11	1 in 1 CARTON	06/21/2011	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA020267	06/21/2011		

**Labeler** - Haleon US Holdings LLC (079944263)