

## **IBUPROFEN- ibuprofen tablet, chewable**

**HyVee Inc**

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### **Hy-Vee, Inc. Children's Ibuprofen Drug Facts**

#### **Active ingredient (in each chewable tablet)**

Ibuprofen 100 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

#### **Purposes**

Pain reliever/fever reducer

#### **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 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, 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**

- mouth or throat burning may occur; give with food or water
- 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 the 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

- **chew or crush tablets completely before swallowing**
- **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.
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**

**Dosing Chart**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Tablets</b>
under 24	under 2	ask a doctor
24-35	2-3	1
36-47	4-5	1 $\frac{1}{2}$
48-59	6-8	2
60-71	9-10	2 $\frac{1}{2}$
72-95	11	3

## Other information

- phenylketonurics: contains phenylalanine 6 mg per tablet
- store between 20-25°C (68-77°F)
- **do not use if printed seal under cap is broken or missing**

## Inactive ingredients

acesulfame potassium, ammonium glycyrrhizin, aspartame, carnauba wax, croscarmellose sodium, FD&C yellow no. 6 aluminum lake, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

## Questions or comments?

**1-800-289-8343**

## Principal Display Panel

Hy•Vee®

Compare To Children's Motrin® Active Ingredient

For Ages 2 to 11 Years

Orange Flavor

Children's Ibuprofen

Chewable Tablets 100 mg

Pain Reliever/Fever Reducer (NSAID)

actual size

LASTS UP TO 8 HOURS

- Chewables

Chew or crush tablets completely before swallowing

24 TABLETS



## IBUPROFEN

ibuprofen tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-461
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>AMMONIUM GLYCERHIZATE</b> (UNII: 3VRD35U26C)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0E1Z)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C YELLOW NO. 6 ALUMINUM LAKE</b> (UNII: GYP6Z2JR6Q)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>SUCCINIC ACID</b> (UNII: AB6MNQ6J6L)	

## Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	L461
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-461-62	1 in 1 CARTON	02/12/2005	
1	NDC:42507-461-24	24 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	ANDA076359	02/12/2005	

**Labeler** - HyVee Inc (006925671)