

IBUPROFEN- ibuprofen tablet, chewable
HyVee Inc

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

Weight (lb)	Age (yr)	Tablets
under 24	under 2	ask a doctor
24-35	2-3	1
36-47	4-5	1 ½
48-59	6-8	2
60-71	9-10	2 ½
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		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	100 mg		
Inactive Ingredients					
Ingredient Name			Strength		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)					
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)					
ASPARTAME (UNII: Z0H242BBR1)					
CARNAUBA WAX (UNII: R12CBM0EIZ)					
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)					
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)					
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)					
MAGNESIUM STEARATE (UNII: 70097M6I30)					
MANNITOL (UNII: 3OWL53L36A)					
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)					
SODIUM LAURYL SULFATE (UNII: 368GB5141J)					
SOYBEAN OIL (UNII: 241ATL177A)					
SUCCINIC ACID (UNII: AB6MNQ6J6L)					
Product Characteristics					
Color	ORANGE	Score	2 pieces		
Shape	ROUND	Size	13mm		
Flavor	ORANGE	Imprint Code	L461		
Contains					
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)