

IBUPROFEN- ibuprofen tablet, chewable
Rite Aid Corporation

Rite Aid Corporation Ibuprofen Tablets, 100 mg Drug Facts

Active ingredient (in each 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

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, 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 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
- 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?

1-800-719-9260

Principal Display Panel

SEE NEW WARNINGS

Compare to the active ingredient of Motrin® Junior Strength
for ages 2-11

junior strength

ibuprofen

ibuprofen tablets, 100 mg

lasts up to 8 hours

orange flavored

pain reliever / fever reducer

(NSAID)

24 CHEWABLE TABLETS



Important: Read all product information before using. Keep this box for important information. This product is for children only.

Drug Facts

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 Ibuprofen 100 mg (NSAID)* Pain reliever/fever reducer
 *nonsteroidal anti-inflammatory drug

Uses temporarily: ■ reduce fever
 ■ relieve minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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 ■ hives ■ facial swelling ■ asthma (wheezing)
 ■ shock ■ skin redness ■ rash ■ blisters
 If an allergic reaction occurs, stop use and seek medical help right away.
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 ■ has had stomach ulcers or bleeding problems
 ■ takes blood thinning (anticoagulant) or steroid drug
 ■ takes other drugs containing prescription or nonprescription NSAID (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.
Some throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

Drug Facts (continued)

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
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Drug Facts (continued)

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Directions
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72-85	11	3

NEP CARTON IS FOR REFERENCE

DISCONTINUED BY RITE AID
 30 HUNTER LANE, CAMPHILL, PA 17011
 IF YOU ARE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

Drug Facts (continued)

Other information
 ■ keep this product or container in a cool, dry place at room temperature (20°-25°C (68°-77°F))
 ■ do not use if the seal is broken or the tablets are missing

Active ingredient ■ see active ingredient information on the other side of the carton for more information
 ■ ibuprofen, aspirin, acetaminophen, or acetaminophen and aspirin
 ■ dextromethorphan, pseudoephedrine, or phenylephrine
 ■ acetaminophen, ibuprofen, and aspirin
 ■ acetaminophen, ibuprofen, and aspirin
 ■ acetaminophen, ibuprofen, and aspirin

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	100 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ASPARTAME (UNII: Z0H242BBR1)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (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:11822-0010-2	1 in 1 CARTON	05/06/2004	
1		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	05/06/2004	

Labeler - Rite Aid Corporation (014578892)

