

SHOPRITE IBUPROFEN IB- ibuprofen tablet, chewable
Wakefern Food Corporation

ShopRite Ibuprofen IB Drug Facts

Active ingredient (in each tablet)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

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, 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

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

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- find the 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
- do not use if printed seal under cap is broken or missing
- store at 20-25°C (68-77°F)
- see end panel for lot number and expiration date

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, prosweet, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Questions or comments?

1-800-SHOPRITE

Principal Display Panel

Compare to: Active Ingredient in Motrin® Junior Strength

SEE NEW WARNINGS INFORMATION

Junior Strength

AGES 2-11

IBUPROFEN IB

Ibuprofen Tablets, 100mg

Pain Reliever – Fever Reducer (NSAID)

Lasts up to 8 hours

24 orange-flavored chewable tablets

Drug Facts (continued)

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Other information

- phenylethanolamine: contains phenylethanamine 6 mg per tablet
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Compare to: Active Ingredient in Motrin® Junior Strength**

SEE NEW WARNINGS INFORMATION

Junior Strength

AGES 2-11



IBUPROFEN IB

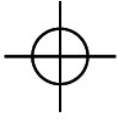
Ibuprofen Tablets, 100mg

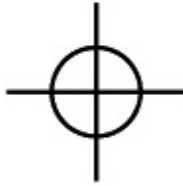
Pain Reliever • Fever Reducer (NSAID)

Lasts up to 8 hours



24 orange-flavored
chewable tablets





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

Drug Facts

Active ingredient (in each tablet) *Purposes*
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*nonsteroidal anti-inflammatory drug

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LOT NO.

EXP.

: 46192 88 C1

Drug Facts (continued)

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- fever or pain gets worse or lasts more than 3 days
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- any new symptoms appear ▶

Drug Facts (contin

Inactive ingredient
glyceryl triacetate, aspartame, sodium, FD&C yellow 6, magnesium stearate, flavors, prosweet, silk soybean oil, succinic acid

Questions or co

KEEP CAP

**This product is not m
Consumer Healthcare

QUALITY GUARANTEE

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KEASBEY, NJ 08832
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SHOPRITE IBUPROFEN IB

ibuprofen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-461
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
ASPARTAME (UNII: Z0H242BBR1)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	

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:41190-461-62	1 in 1 CARTON		
1		24 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076359	07/02/2013	

Labeler - Wakefern Food Corporation (069722418)

Revised: 9/2013

Wakefern Food Corporation