

UP AND UP CHILDRENS IBUPROFEN- ibuprofen tablet, chewable
Target Corporation

Target Corporation 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

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

- **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, D&C red no. 27 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Questions?

Call 1-888-547-7400

Package/Label Principal Display Panel

Compare to active ingredient in Children's Motrin®

children's

ibuprofen

chewable tablets, 100 mg

pain reliever/fever reducer (NSAID)

chewables

AGES 2 TO 11 YEARS

LASTS UP TO 8 HOURS

GRAPE FLAVOR

24 TABLETS

24 CHEWABLE TABLETS

chew or crush tablets completely before swallowing

52162 UNV C6

CODE AREA



KEEP CARTON FOR REFERENCE

NDC 11673-741-82
Compare to active ingredient in Children's Motrin®**

children's ibuprofen

chewable tablets, 100 mg
pain reliever/fever reducer (NSAID)
chewables



AGES
2 TO 11
YEARS

LASTS UP TO
8
HOURS



GRAPE
FLAVOR

24
TABLETS

24 CHEWABLE TABLETS

chew or crush tablets completely before swallowing

Drug Facts (continued)

- 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

- chew or crush tablets completely before swallowing
- this product does not contain dextrose or complete warnings
- do not give more than directed
- if redness, 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	1½
48-59	6-8	2
60-71	9-10	2½
72-85	11	3

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

Drug Facts

Active ingredient (in each chewable tablet): **Purposes**
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, headache and toothaches

Warnings

Allergies: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
■ hives ■ facial swelling ■ asthma (wheezing)
■ shock ■ skin rash ■ dizziness ■ dizziness

If an allergic reaction occurs, stop use and seek medical help right away. Stomach bleeding warning: The production of 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 drug (coumadin) or aspirin drug
■ takes other drugs containing prescription or over-the-counter NSAIDs (aspirin, ibuprofen, naproxen, or others)
■ takes more or for longer 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 heart warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Contact doctor promptly. Do not use more than 2 days or administer to children under 6 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
- child has a history of stomach problems, such as heart burn
- child has problems or symptoms of infection from being pain relievers or fever reducers
- child has not been drinking fluids
- child has had a lot of fluid due to vomiting or diarrhea
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, or fluid stroke
- child has asthma ■ child is taking a drug to

Ask a doctor or pharmacist to help use it 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
- table 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:
■ black stool ■ vomit blood ■ has bloody or black stools
- the stomach pain that does not get better
- child has symptoms of heart problems or stroke:
■ chest pain ■ trouble breathing
■ weakness in part or all of body
■ slurred speech ■ leg swelling

Drug Facts (continued)

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: acacia, croscarmellose sodium, glycerol, hydroxypropyl methylcellulose, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Questions? Call 1-888-547-7400

**This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Children's Motrin®.

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GLUTEN FREE

UP AND UP CHILDRENS IBUPROFEN
ibuprofen tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-741
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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	PURPLE (lavender)	Score	2 pieces
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	L521
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-741-62	1 in 1 CARTON	08/05/2019	
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	08/05/2019	

