

JUNIOR STRENGTH ADVIL- ibuprofen tablet, chewable
Wyeth Consumer Healthcare LLC

Junior Strength Advil (Ibuprofen) Chewables

DRUG FACTS

ACTIVE INGREDIENT (IN EACH TABLET)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Fever reducer/Pain reliever

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 the 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 any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to the child
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has a history of stomach problems, such as heartburn
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- 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

- 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
- 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.

DIRECTIONS

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- find right dose on chart. If possible, use weight to dose; otherwise use age.

- repeat dose every **6-8 hours**, if needed
- do not use more than **4 times a day**

Dosing Chart

Weight (lb)	Age (yr)	Dose (tablets)
under 24 lb	under 2 yr	ask a doctor
24-35 lb	2-3 yr	1 tablet
36-47 lb	4-5 yr	1 ½ tablets
48-59 lb	6-8 yr	2 tablets
60-71 lb	9-10 yr	2 ½ tablets
72-95 lb	11 yr	3 tablets

OTHER INFORMATION

- **Phenylketonurics**: contains phenylalanine 4.2 mg per tablet
- one dose lasts 6-8 hours
- store at 20-25°C (68-77°F)
- see side of box for lot number and expiration date

INACTIVE INGREDIENTS

aspartame, cellulose, colloidal silicon dioxide, D&C red no. 30 aluminum lake, FD&C blue no. 2 aluminum lake, gelatin, magnesium stearate, mannitol, microcrystalline cellulose, modified corn starch, natural and artificial flavors, sodium starch glycolate

QUESTIONS OR COMMENTS?

call toll-free **1-800-88-ADVIL** or ask your pharmacist, doctor or health care professional

PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Label


Junior Strength
Advil®

Ibuprofen Tablets, 100 mg
Pain Reliever/
Fever Reducer (NSAID)

READ AND KEEP CARTON

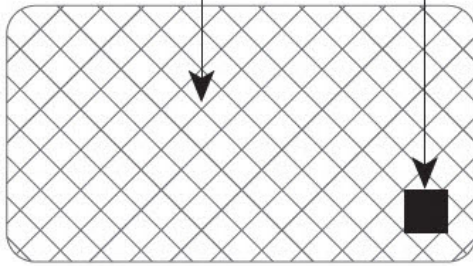
Grape Flavor
24 CHEWABLE TABLETS

Pfizer, Madison, NJ 07940 USA
© 2018 Pfizer Inc.

Junior Strength Advil® Ibuprofen Tablets, 100 mg Pain Reliever/ Fever Reducer (NSAID)	Uses temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches. Warnings: Ask doctor before use if child is under a doctor's care for a serious condition; taking other drugs or has stomach problems. 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 allergic reaction occurs, stop use, seek medical help right away. Do not use if child has ever had an allergic reaction to any pain reliever/fever reducer. Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if the 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. Phenylketonurics: contains phenylalanine 4.2 mg per tablet. Directions: This product does not contain directions or complete warnings for adult use. Do not give more than directed. Find right dose on chart. If possible, use weight to dose; otherwise use age. Repeat dose every 6-8 hours, if needed. Do not use more than 4 times a day. Store at 20-25°C (68-77°F). Questions? call 1-800-88-ADVIL. PAA100319																					
READ AND KEEP CARTON Grape Flavor 24 CHEWABLE TABLETS Pfizer, Madison, NJ 07940 USA © 2018 Pfizer Inc.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Weight (lb)</th> <th>Age (yr)</th> <th>Dose (tablets)</th> </tr> </thead> <tbody> <tr> <td>under 24 lb</td> <td>under 2 yr</td> <td>ask a doctor</td> </tr> <tr> <td>24-35 lb</td> <td>2-3 yr</td> <td>1 tablet</td> </tr> <tr> <td>36-47 lb</td> <td>4-5 yr</td> <td>1 ½ tablets</td> </tr> <tr> <td>48-59 lb</td> <td>6-8 yr</td> <td>2 tablets</td> </tr> <tr> <td>60-71 lb</td> <td>9-10 yr</td> <td>2 ½ tablets</td> </tr> <tr> <td>72-95 lb</td> <td>11 yr</td> <td>3 tablets</td> </tr> </tbody> </table>	Weight (lb)	Age (yr)	Dose (tablets)	under 24 lb	under 2 yr	ask a doctor	24-35 lb	2-3 yr	1 tablet	36-47 lb	4-5 yr	1 ½ tablets	48-59 lb	6-8 yr	2 tablets	60-71 lb	9-10 yr	2 ½ tablets	72-95 lb	11 yr	3 tablets	
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PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Carton

Junior Strength
 Advil®
 Chewables
 Ibuprofen Tablets, 100 mg
 Pain Reliever/Fever Reducer (NSAID)
 FEVER Aches & Pains
 NEW!
 Now for
 Ages 2-11
 LASTS UP TO
 8
 HOURS
 Grape
 24 Chewable Tablets



Drug Facts (continued)

- see side of box for lot number and expiration date
- store at 20-25°C (68-77°F)

Inactive ingredients

aspartame, cellulose, croscollon, croscollon dioxide, D & C red no. 30 aluminum lake, FD & C blue no. 2 aluminum lake, gelatin, magnesium stearate, mannitol, methylcellulose, modified corn starch, natural and artificial flavors, sodium starch glycolate

Questions or comments?

call toll-free 1-800-88-ADVIL or ask your pharmacist, doctor or health care professional

For most recent product information, visit www.Advill.com
Pfeizer, Madison, NJ 07940 USA © 2018 Pfizer Inc.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- repeat dose every 6-8 hours, if needed
- do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (yr)	Dose (tablets)
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48-59 lb	6-8 yr	2 tablets
60-71 lb	9-10 yr	2 ½ tablets
72-95 lb	11 yr	3 tablets

Other information

- Phenylephrine: contains phenylephrine 4.2 mg per tablet
- one dose lasts 6-8 hours

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.



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NEW! Now for Ages 2-11

Junior Strength Advil® Chewables

Ibuprofen Tablets, 100 mg
Pain Reliever/Fever Reducer (NSAID)

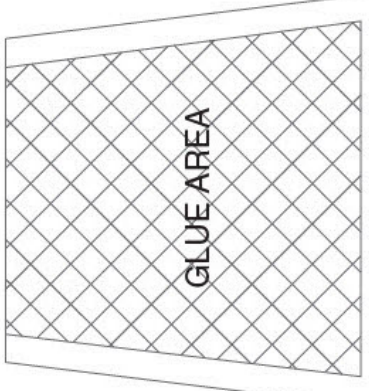
FEVER Aches & Pains

LASTS UP TO 8 HOURS

Advil 100 Grape

24 Chewable Tablets

PA1100320



NEW! Now for Ages 2-11

Junior Strength Advil® Chewables

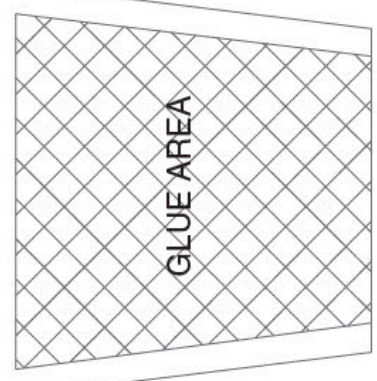
Ibuprofen Tablets, 100 mg
Pain Reliever/Fever Reducer (NSAID)

FEVER Aches & Pains

LASTS UP TO 8 HOURS

Advil 100 Grape

24 Chewable Tablets



Drug Facts (continued)

- child has problems or serious side effects from taking pain relievers or fever reducers
- child has a history of stomach problems such

Drug Facts (continued)

Symptoms may include:

- child has a history of stomach problems, such as heartburn
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- 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

- take with food or milk if stomach upset occurs

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

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 the 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

Important: Read all product information before using. Keep this carton for important information. This product is intended for use in children ages 2 years - 11 years.



PAA100318

Drug Facts

Active ingredient (in each tablet)	Purpose
Ibuprofen 100 mg (NSAID)*.....	Fever reducer/ Pain reliever
*nonsteroidal anti-inflammatory drug	

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.

LIFT HERE

Drug Facts (continued)

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 any other pain reliever/fever reducer
- right before or after heart surgery

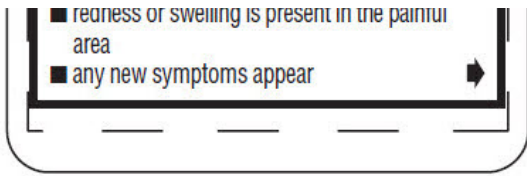
Ask a doctor before use if

- stomach bleeding warning applies to the child

Drug Facts (continued)

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
- child does not get any relief within first day (24 hours) of treatment
- fever or pain gets worse or lasts more than 3 days



JUNIOR STRENGTH ADVIL

ibuprofen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0179
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
ASPARTAME (UNII: Z0H242BBR1)	
CELLACEFATE (UNII: F2O5O2O19F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	PURPLE (light purple)	Score	2 pieces
Shape	ROUND (mottled round purple tablet)	Size	10mm
Flavor	GRAPE	Imprint Code	Advil;100
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0179-20	1 in 1 CARTON	06/01/2011	
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
NDA	NDA020944	06/01/2011	

Labeler - Wyeth Consumer Healthcare LLC (828831730)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0573-0179) , LABEL(0573-0179) , MANUFACTURE(0573-0179) , PACK(0573-0179)

Revised: 2/2019

Wyeth Consumer Healthcare LLC