

**JUNIOR STRENGTH ADVIL- ibuprofen tablet, chewable**  
**GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

-----  
**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**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (tablets)</b>
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, cellacefate, 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**

### **Junior Strength**

**Advil®**

Chewables

Ibuprofen Tablets, 100 mg

Pain Reliever/Fever Reducer (NSAID)

### **FEVER Aches & Pains**

#### **NEW!**

Now for

Ages 2-11

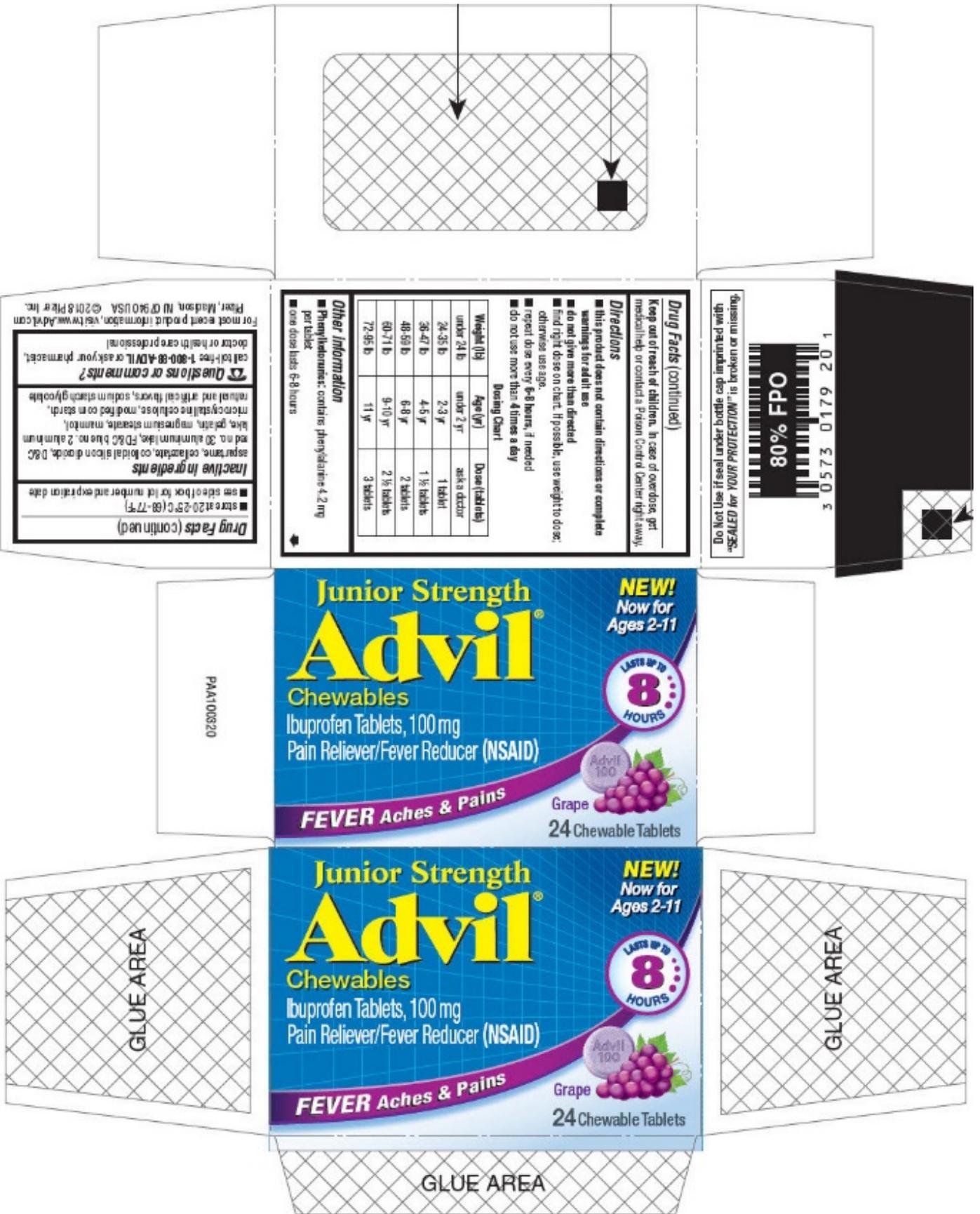
LASTS UP TO

**8**

HOURS

Grape

**24** Chewable Tablets



**Drug Facts (continued)**  
 ■ store at 20-25°C (68-77°F)  
 ■ see side of box for lot number and expiration date  
**Inactive ingredients**  
 aspartame, cellulose, croscollon 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, talc, 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.Advil.com  
 Pfizer, 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 do so; 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**  
 ■ **Preservatives:** contains phenylethylamine 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.

**80% FPO**

3 0573 0179 20 1

**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:  
 ■ hives ■ facial swelling

as nearburn

- 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

- asthma (wheezing)
- skin reddening
- blisters
- 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

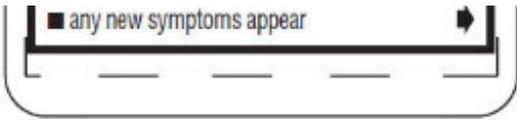
**Ask a doctor before use if**

- 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
- redness or swelling is present in the painful area



## JUNIOR STRENGTH ADVIL

ibuprofen tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0573-0179
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>CELLACEFATE</b> (UNII: F2O5O2O19F)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

### Product Characteristics

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

### 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** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

## 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: 1/2023

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC