# JUNIOR STRENGTH ADVIL- ibuprofen tablet, chewable Proficient Rx LP

-----

## 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**

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

## **Dosing Chart**

## **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 - 100 mg Tablet Bottle Label

Junior Strength Advil<sup>®</sup> Ibuprofen Tablets, 100 mg Pain Reliever/ Fever Reducer (NSAID)

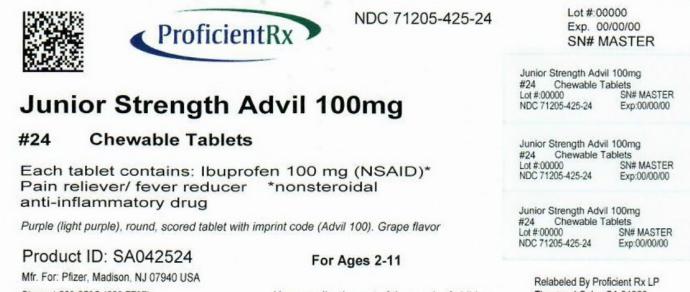
**READ AND KEEP CARTON** 

Grape Flavor 24 CHEWABLE TABLETS

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320



Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Thousand Oaks, CA 91320

JUNIOR STRENGTH A				
buprofen tablet, chewable				
Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-425(NDC:0573-0179	
Route of Administration	ORAL			
Active Ingredient/Active M	oiety			
0	oiety 1gredient Name		Basis of Strength	Strength
J. II	ngredient Name	10 Q M)	<b>Basis of Strength</b> IBUPROFEN	Strength
J. II	ngredient Name	10 Q M)		
IBUPROFEN (UNII: WK2XYI10QM) (	ngredient Name	(10 Q M)		
II IBUPROFEN (UNII: WK2XYI10QM) (	ngredient Name	10 Q M)		
II IBUPROFEN (UNII: WK2XYI10QM) (	ngredient Name			
J. II	<b>igredient Name</b> IBUPROFEN - UNII:WK2XYI			100 mg

SILICON DIO XIDE	,					
D&C RED NO. 30 (U	NII: 2S42T2808B)					
FD&C BLUE NO. 2	UNII: L06K8R7DQK)					
GELATIN, UNSPEC	F <b>IED</b> (UNII: 2G86QN32	7L)				
MAGNESIUM STEA	<b>EATE</b> (UNII: 70097M613	30)				
MANNITOL (UNII: 3	DWL53L36A)					
MICRO CRYSTALL	NE CELLULOSE (UNII	: OP1R32D61U)				
SODIUM STARCH C	LYCOLATE TYPE A F	<b>POTATO</b> (UNII: 5856J3G2A2)				
Product Charac	teristics					
Color H	PURPLE (light purple)			Score		2 pieces
Shape I	ROUND (mottled round purple tablet)			Size		10 mm
Flavor	GRAPE			Imprint Code		Advil;100
Contains						
Packaging						
# Item Code	Pack	age Description	Mar	keting Start Date	Mark	eting End Date
1 NDC:71205-425-24	1 in 1 CARTON		03/11/	03/11/2020		
1	24 in 1 BOTTLE; Typ	e 0: Not a Combination Product				
Marketing In	formation					
Marketing Catego	ry Application Nu	mber or Monograph Citation	Ma	rketing Start Date	Marl	keting End Date
NDA	NDA020944		06/0	1/2011		

Labeler - Proficient Rx LP (079196022)

## Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-425), RELABEL(71205-425)

Revised: 3/2020

Proficient Rx LP