

**CHILDRENS IBUPROFEN- ibuprofen tablet, chewable**  
**Publix Super Markets Inc**

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**Publix Super Markets, Inc. 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**

<b>Dosing Chart</b>		
<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Tablets</b>
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 68-77°F (20-25°C)
- **do not use if printed seal under cap is broken or missing**

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

## Package/Label Principal Display Panel

AGES 2 – 11 YEARS

CHILDREN'S

ibuprofen

IBUPROFEN CHEWABLE TABLETS, 100 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

Chewables

Orange flavored

Lasts up to 8 hours

Chew or crush tablets completely before swallowing

ACTUAL SIZE

24 CHEWABLE TABLETS

Compare to the active ingredient in Children's Motrin®



ibuprofen tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-801
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ASPARTAME (UNII: Z0H242BBR1)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (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

<b>Color</b>	ORANGE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	L461
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-801-62	1 in 1 CARTON	03/12/2020	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA076359	03/12/2020	

Revised: 3/2020

Publix Super Markets Inc