

**PROFEN IB INFANTS- ibuprofen suspension**  
**Publix Super Markets Inc**

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**Publix Super Markets, Inc. Profen IB Drops Drug Facts**

**Active ingredient (in each 1.25 mL)**

Ibuprofen 50 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**

- give 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

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- shake well before using
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- mL = milliliter
- measure with the dosing device provided. Do not use with any other device.
- dispense liquid slowly into the child's mouth, toward the inner cheek
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day

| <b>Dosing Chart</b> |                  |                  |
|---------------------|------------------|------------------|
| <b>Weight (lbs)</b> | <b>Age (mos)</b> | <b>Dose (mL)</b> |
| under 6 mos         |                  | ask a doctor     |
| 12-17 lbs           | 6-11 mos         | 1.25 mL          |
| 18-23 lbs           | 12-23 mos        | 1.875 mL         |

## Other information

- store at 20-25°C (68-77°F)
- do not freeze
- **do not use if printed neckband is broken or missing**

## Inactive ingredients

anhydrous citric acid, FD&C red #40, glycerin, hypromellose, natural and artificial berry flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

## Principal Display Panel

FOR AGES 6 TO 23 MONTHS

INFANTS'

profen IB drops

CONCENTRATED DROPS

IBUPROFEN ORAL SUSPENSION 50 mg PER 1.25 mL

Pain reliever / Fever reducer (NSAID)

Lasts up to 8 hours

USE ONLY WITH ENCLOSED SYRINGE

BERRY FLAVOR

0.5 FL OZ (15 mL)

Compare to Motrin® Infants' Drops active ingredient



## PROFEN IB INFANTS

ibuprofen suspension

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:56062-057 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength         |
|--|-------------------|------------------|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN         | 50 mg in 1.25 mL |

### Inactive Ingredients

| Ingredient Name                          | Strength |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) |          |

|   |  |
|---|--|
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA) |  |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)            |  |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)       |  |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)      |  |
| <b>WATER</b> (UNII: 059QF0KO0R)               |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)     |  |
| <b>SORBITOL</b> (UNII: 506T60A25R)            |  |
| <b>SUCROSE</b> (UNII: C151H8M554)             |  |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)         |  |

**Product Characteristics**

|                 |              |                     |  |
|-----------------|--------------|---------------------|--|
| <b>Color</b>    | PINK (light) | <b>Score</b>        |  |
| <b>Shape</b>    |              | <b>Size</b>         |  |
| <b>Flavor</b>   | BERRY        | <b>Imprint Code</b> |  |
| <b>Contains</b> |              |                     |  |

**Packaging**

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:56062-057-05 | 1 in 1 CARTON  | 06/29/2001           |                    |
| 1 |                  | 15 mL 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               | ANDA075217                               | 06/29/2001           |                    |

**Labeler** - Publix Super Markets Inc (006922009)