**UP AND UP CHILDRENS IBUPROFEN- ibuprofen suspension**
**Target Corporation**

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**Target Corporation Children's Ibuprofen Oral Suspension Drug Facts**

**Active ingredient (in each 5 mL)**

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

**Purposes**

Pain reliever/fever reducer

**Uses**

temporarily:

- relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- reduces fever

**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
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

Dosing Chart

| Weight (lb) | Age (yr) | Dose (mL)** |
|---|---|---|
| under 24 lbs | under 2 years | ask a doctor |
| 24-35 lbs | 2-3 years | 5 mL |
| 36-47 lbs | 4-5 years | 7.5 mL |
| 48-59 lbs | 6-8 years | 10 mL |
| 60-71 lbs | 9-10 years | 12.5 mL |
| 72-95 lbs | 11 years | 15 mL |

**or as directed by a doctor

**Other information**

- each 5 mL contains: sodium 2 mg
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not freeze

**Inactive ingredients**

anhydrous citric acid, FD&C red #40, glycerin, high fructose corn syrup, hypromellose, natural and artificial bubblegum flavors, polysorbate 80, purified water, sodium benzoate, sorbitol solution, xanthan gum

**Questions?**

Call 1-888-547-7400

**Principal Display Panel**

see new warnings

Compare to active ingredient in Children's Motrin® Bubble Gum Flavor

children's ibuprofen

oral suspension

100 mg per 5 mL

pain reliever/fever reducer (NSAID)

alcohol free

LASTS UP TO 8 HOURS

BUBBLEGUM FLAVOR

AGES 2 TO 11 YEARS

4 FL OZ (118 mL)

# UP AND UP CHILDRENS IBUPROFEN

ibuprofen suspension

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11673-166 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **IBUPROFEN** (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 100 mg in 5 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **HIGH FRUCTOSE CORN SYRUP** (UNII: XY6UN3QB6S) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | PINK (light) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | BUBBLE GUM | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:11673-166-26 | 1 in 1 CARTON | 06/12/2009 | |
| **1** | | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:11673-166-28 | 1 in 1 CARTON | 08/24/2012 | 12/15/2014 |
| **2** | | 148 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:11673-166-34 | 1 in 1 CARTON | 02/19/2013 | |
| **3** | | 237 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 | ANDA074937 | 06/12/2009 | |

## Labeler - Target Corporation (006961700)

Revised: 10/2017 Target Corporation