

**UP AND UP DYE FREE INFANTS CONCENTRATED IBUPROFEN-  
ibuprofen suspension/ drops  
Sixarp, LLC**

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**Target Corporation Concentrated Ibuprofen Oral Suspension 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

### **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**
- **Dosing Chart**

| Weight (lbs) | Age (mos) | Dose (mL)    |
|--------------|-----------|--------------|
| 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, glycerin, hypromellose, natural and artificial berry flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

### Questions?

**Call 1-888-547-7400**

### Principal Display Panel

see new warnings

Compare to active ingredient in Motrin® Infants' Drops Dye-Free

for ages 6 mos. to 23 mos.

dye-free

infants'

concentrated ibuprofen

oral suspension

50 mg per 1.25 mL

pain reliever/fever reducer (NSAID)

concentrated drops

non-staining

LASTS UP TO 8 HOURS

BERRY FLAVOR

AGES 6 TO 23 MONTHS

1 FL OZ (30 mL)

Use only with enclosed syringe.

see new warnings NDC 11673-255-10

Compare to active ingredient in Motrin® Infants' Drops Dye-Free\*\* for ages 6 mos. to 23 mos.

# dye-free infants' concentrated ibuprofen

oral suspension  
50 mg per 1.25 mL  
pain reliever/fever reducer (NSAID)  
concentrated drops  
non-staining



LASTS UP TO  
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AGES  
**6 TO 23**  
MONTHS

Use only with enclosed syringe.

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ACTUAL SIZE



Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 6 months to 23 months of age.

### Drug Facts

**Active ingredient (in each 1.25 mL)** *Purposes*  
Ibuprofen 50 mg (NSAID) .....Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**Uses temporarily:** ■ reduces fever  
■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

### Drug Facts (continued)

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**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

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**When using this product**  
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**Stop use and ask a doctor if**  
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■ slurred speech ■ leg swelling  
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### Drug Facts (continued)

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■ do not use if printed neckband is broken or missing

**Inactive ingredients**  
anhydrous citric acid, glycerin, hypromellose, natural and artificial berry flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

#### Questions? Call

1-888-547-7400

\*\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Motrin® Infants' Drops Dye-Free.

**GLUTEN FREE**



25510 UW C6

## UP AND UP DYE FREE INFANTS CONCENTRATED IBUPROFEN

ibuprofen suspension/ drops

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59368-003 |
| <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 | 50 mg in 1.25 mL |
|---|-----------|------------------|

### Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)              |          |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)         |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)        |          |
| <b>WATER</b> (UNII: 059QF0K00R)                 |          |
| <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>    | white (Opaque) | <b>Score</b>        |  |
| <b>Shape</b>    |                | <b>Size</b>         |  |
| <b>Flavor</b>   | BERRY (mixed)  | <b>Imprint Code</b> |  |
| <b>Contains</b> |                |                     |  |

### Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59368-003-01 | 1 in 1 CARTON  | 07/08/2009           |                    |
| 1 |                  | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:59368-003-02 | 2 in 1 CARTON  | 08/23/2018           |                    |
| 2 |                  | 30 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                               | 07/08/2009           |                    |

**Labeler** - Sixarp, LLC (016329513)

### Establishment

| Name        | Address | ID/FEI    | Business Operations                       |
|-------------|---------|-----------|---|
| Sixarp, LLC |         | 016329513 | manufacture(59368-003) , label(59368-003) |

