

CHILDRENS IBUPROFEN 572 - ibuprofen suspension/ drops
Family Dollar Services, Inc.

Family Wellness Children's Ibuprofen Oral Suspension 572

ACTIVE INGREDIENT (in each 5 mL)

Ibuprofen, USP 100 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USE(S)

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
- asthma (wheezing)
- skin reddening
- facial swelling
- shock
- 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

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

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

STOP USE AND ASK 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
- 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

Dosing Chart

| Weight (lb) | Age (yr) | Dose (mL)* |
|-------------|---------------|--------------|
| under 24 | 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
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or if printed inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

INACTIVE INGREDIENTS

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum.

QUESTIONS OR COMMENTS?

Call 1-609-860-2600 (Monday-Friday 8 am -4 pm)

PRINCIPAL DISPLAY PANEL

FAMILY Wellness

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S MOTRIN®*

Children's Ibuprofen

Oral Suspension

Ages 2 to 11 Years

USP 100 mg per 5 mL

Pain Reliever/Fever Reducer (NSAID)

8 Hour

Alcohol Free

BUBBLE GUM FLAVOR

4 FL OZ (120mL)



Severe 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 7 days or administer to children under 3 years of age unless directed by a 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 had a lot of blood or had one or more of the following: **Child** has had blood pressure, liver disease, low stomach acid, or kidney disease. **Child** has asthma. **Child** is taking a diuretic. **Ask a doctor or pharmacist** before use if the child is on or will be on a doctor's care for any serious condition, including any other drug.

When using this product: Use with food or milk. If stomach upset occurs, the risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Stop use and ask a doctor if **child** experiences any of the following signs of stomach bleeding: **Red** stool; **black** stool; **red** or **black** stool; **stomach** pain that does not get better.

Child does not get any relief within first day (24 hours) of treatment. **Throat** or pain gets worse or lasts more than 7 days. **Stomach** or vomiting is present in the child's care. **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. 74-0402-04-022.

Directions: This product does not contain directions or complete warnings for adult use. **Do not** give more than directed. **Always** use before using **any** other **NSAID**. **Use** right dose on chart. If possible, use weight to dose; otherwise use age. **Do not** use if child is taking any other drug. **Do not** use if child is taking any other drug. **Do not** use more than 6 times a day. **Do not** use original cap to maintain child resistance.

NON-PRINTING AREA

| Dosing Chart | | |
|--------------|---------------|--------------|
| Weight (lb) | Age (yr) | Dose (mL)* |
| under 24 | under 2 years | ask a doctor |
| 24-35 | 2-3 years | 5 mL |
| 36-47 | 4-6 years | 7.5 mL |
| 48-59 | 6-8 years | 10 mL |
| 60-71 | 9-10 years | 12.5 mL |
| 72-83 | 11 years | 15 mL |

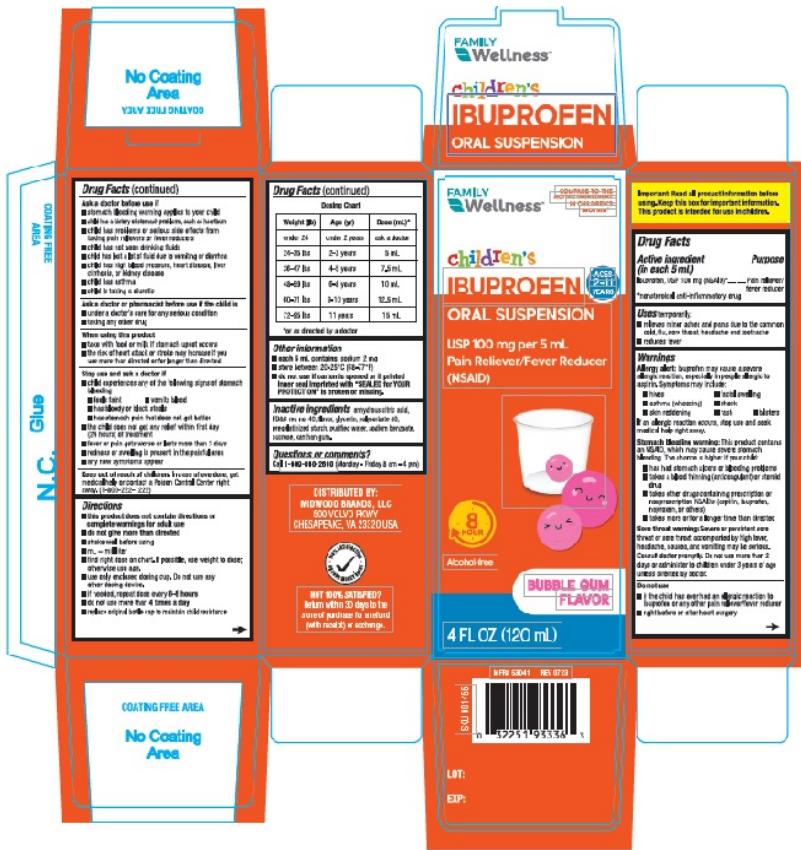
*or as directed by a doctor

Other information:

- Each 5 mL contains sodium 2 mg
- Store between 20-25°C (68-77°F)
- Do not use if printed inner seal/imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.

Active ingredients: ibuprofen, citric acid, FD&C red no. 40, flavor, glycerin, polyorbene 80, polyorbene 90, purified water, sodium benzoate, sodium saccharin, sucrose.

Contains or contains? Call 1-800-860-2600 (Monday - Friday 8 am - 4 pm)



CHILDRENS IBUPROFEN 572

ibuprofen suspension/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55319-929 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | 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: PDC6A3COOX) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3S) | |

| | |
|---|--|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SUCROSE (UNII: C151H8M554) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | BUBBLE GUM | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55319-929-03 | 1 in 1 CARTON | 04/18/2024 | |
| 1 | | 120 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 | ANDA210149 | 04/18/2024 | |

Labeler - Family Dollar Services, Inc. (024472631)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| Guardian Drug Company | | 119210276 | MANUFACTURE(55319-929) |

Revised: 4/2024

Family Dollar Services, Inc.