INFANTS IBUPROFEN- ibuprofen suspension
Proficient Rx LP

Ibuprofen Oral Suspension, USP

Drug Facts

Active ingredient (in each 1.25 mL)

Ibuprofen 50 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

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 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

Stop use and ask a doctor if

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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 to 8 hours**
- do not use more than **4 times a day**

Dosing Chart		
Weight (lb)	**Age (mos)**	**Dose (mL)**
under 6 mos		ask a doctor
12 to 17 lbs	6 to 11 mos	1.25 mL
18 to 23 lbs	12 to 23 mos	1.875 mL

Other information

- store between 20° to 25°C (68° to 77°F)
- **do not use if plastic bottle wrap imprinted "sealed for your protection" is broken or missing**

Inactive ingredients

carboxymethylcellulose sodium, citric acid anhydrous, glycerin, microcrystalline cellulose, natural and artificial berry fruit punch type flavor, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, and xanthan gum.

Questions or Comments?

1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

Principal Display Panel

Actavis

Compare to the active ingredient in Concentrated Motrin® Infants' Drops†

NDC 71205-110-30

See New Warnings

For Ages 6 Mos. to 23 Mos.

Infants' Ibuprofen

Concentrated Ibuprofen Oral Suspension, USP

(NSAID)

50 mg per 1.25 mL

Pain Reliever

Fever Reducer

Lasts up to 8 hours

Non-Staining

Use only with enclosed syringe

Dye-Free Berry Flavor

Alcohol Free

½ FL OZ (15 mL)

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

INFANTS IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71205-110(NDC:45963-125)
Route of Administration	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**
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Other Ingredients		
Ingredient Kind	**Ingredient Name**	**Quantity**
Does not contain	**ALCOHOL** (UNII: 3K9958V90M)	0 in 1.25 mL

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71205-110-15	1 in 1 CARTON	09/03/2018	
1		15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:71205-110-30	1 in 1 CARTON	09/03/2018	
2		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079058	05/11/2010	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-110)