INFANTS IBUPROFEN - ibuprofen suspension
Aurohealth LLC

Ibuprofen Oral Suspension USP 50 mg per 1.25 mL

Drug Facts

Active ingredient (in each 1.25 mL)

Ibuprofen USP 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 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

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 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 carton is opened or seal under cap is broken or missing**

Inactive ingredients

acesulfame potassium, art raspberry flavor (contains propylene glycol), citric acid anhydrous, FD&C Red No. 40, glycerin, hypromellose, noncrystallizing sorbitol solution, polysorbate 80, pregelatinized starch (potato), purified water, sodium benzoate, sucrose, xanthan gum

Questions or comments?

Call 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/19/1993

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 FL OZ (30 mL) Container Label

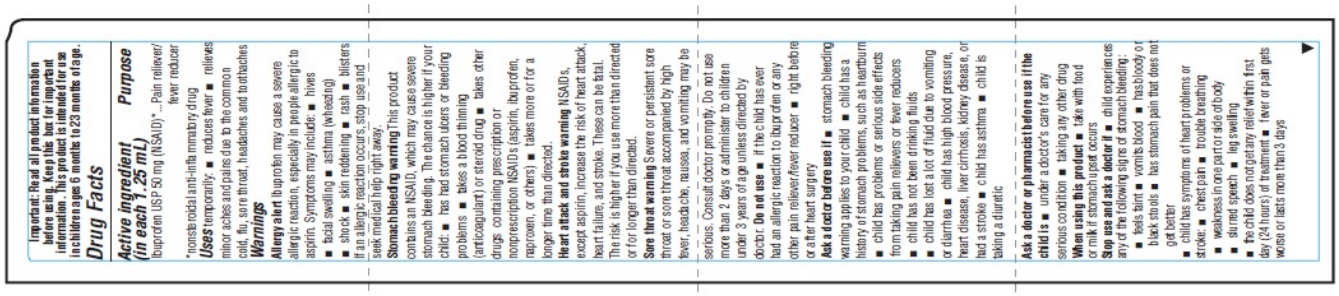
AUROHEALTH
NDC 58602-227-07
For Ages 6 Mos. to 23 Mos.
Concentrated Infants' Drops
Ibuprofen Oral Suspension,
USP (NSAID)
50 mg per 1.25 mL
Pain Reliever/Fever Reducer (NSAID)
Concentrated Drops
Lasts up to 8 hours
Use only with enclosed syringe.
Berry Flavor
1 fl oz (30 mL)

Base

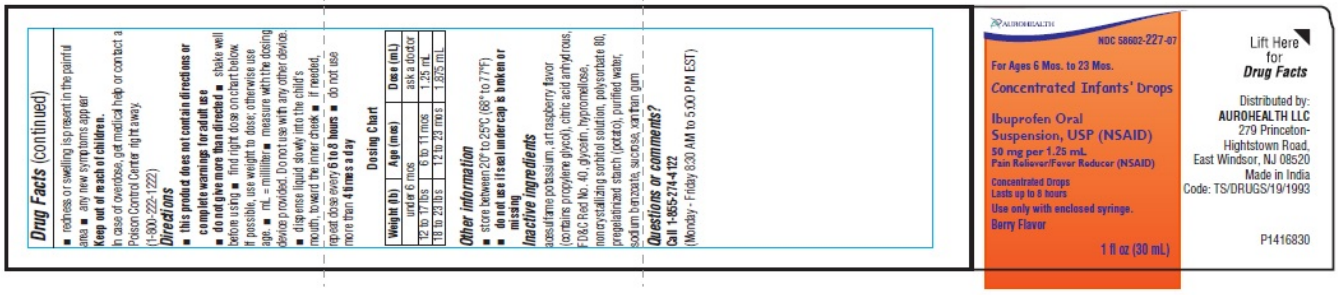
Booklet Placement

Booklet

Page #2 (Back of Cover) | Page #3 | Page #4 | Page #5



Page #6 | Page #7 | Page #8 | Cover (Page #1)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 FL OZ (30 mL) Container Carton Label

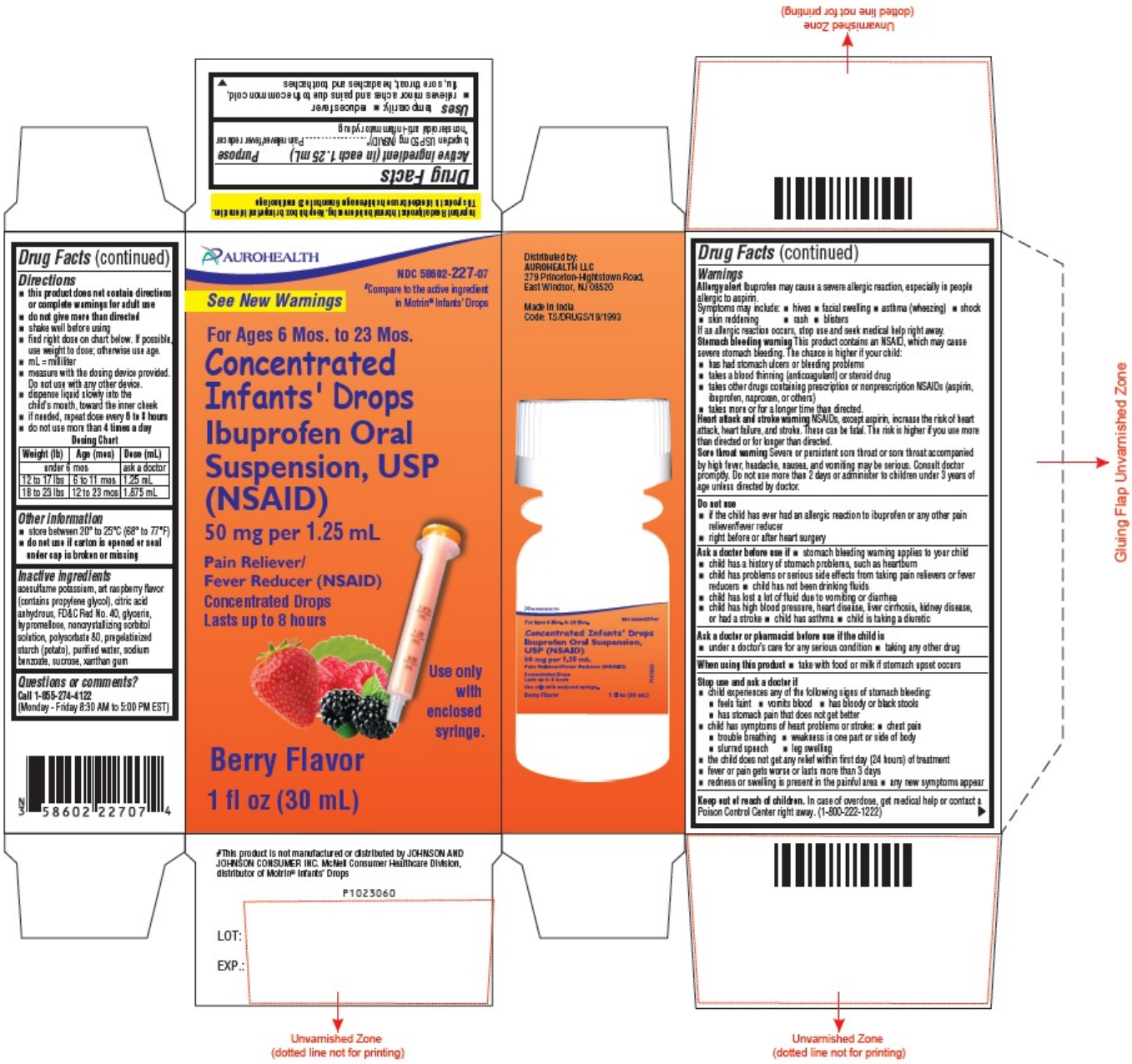
AUROHEALTH
NDC 58602-227-07
#Compare to the active ingredient in Motrin® Infants' Drops
See New Warnings

For Ages 6 Mos. to 23 Mos.
Concentrated
Infants' Drops
Ibuprofen Oral
Suspension, USP
(NSAID)
50 mg per 1.25 mL

Pain Reliever/
Fever Reducer (NSAID)
Concentrated Drops
Lasts up to 8 hours

Use only
with
enclosed
syringe.

Berry Flavor
1 fl oz (30 mL)



INFANTS IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-227
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2208 (4000 MPA.S) (UNII: 39J80LT57T)	
NONCRYSTALLIZING SORBITOL SOLUTION (UNII: 9E0S3UM200)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, POTATO (UNII: 8I089SAH3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK (Light Pink to Pink)	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-227-04	1 in 1 CARTON	04/08/2024	
1		15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-227-07	1 in 1 CARTON	04/08/2024	
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	ANDA213506	04/08/2024	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-227) , MANUFACTURE(58602-227)

Revised: 4/2024

Aurohealth LLC