CHILDRENS IBUPROFEN - ibuprofen suspension
Central Texas Community Health Centers

Children's Ibuprofen Oral Suspension, USP

ACTIVE INGREDIENT

(in each 5 mL = 1 teaspoon)

Ibuprofen, USP 100 mg (NSAID)**

**nonsteroidal anti-inflammatory drug

PURPOSE

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

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 any other pain reliever/fever reducer
- right before or after heart surgery

ASK 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, or kidney disease
- child has asthma
- child is taking a diuretic

ASK 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 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
- the child does not get any relief within the 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. If possible, use weight to dose; otherwise use age.
- use only enclosed measuring cup
- 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 (tsp or mL)
under 2 years		ask a doctor
24 – 35 lbs	2 – 3 years	1 tsp or 5 mL
36 – 47 lbs	4 – 5 years	1½ tsp or 7.5 mL
48 – 59 lbs	6 – 8 years	2 tsp or 10 mL
60 – 71 lbs	9 – 10 years	2½ tsp or 12.5 mL
72 – 95 lbs	11 years	3 tsp or 15 mL

Other information

- each teaspoon contains: **sodium 2 mg**
- **do not use if printed neckband is broken or missing**
- store between 20 - 25°C (68 - 77°F)
- see bottom panel for lot number and expiration date

INACTIVE INGREDIENT

Berry flavor: citric acid, D&C yellow #10, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

Dye free berry flavor: citric acid, flavors, glycerin, hypromellose, polysorbate-80, purified water, sodium benzoate, sucrose, xanthan gum

Bubble gum flavor: artificial bubble gum flavor, citric acid, FD&C red #40, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum.

QUESTIONS?

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

PRINCIPAL DISPLAY PANEL - 100 MG/5 ML Bottle Label

Austin/Travis Co. Health & Human Services Dept.
1000 Toyath St Austin, TX 78702 512-972-6206

IBUPROFEN
100MG/5ML
SUSP.

Date:

Name:
Dr.

TAKE ___ ML BY MOUTH ___ TIMES A DAY.

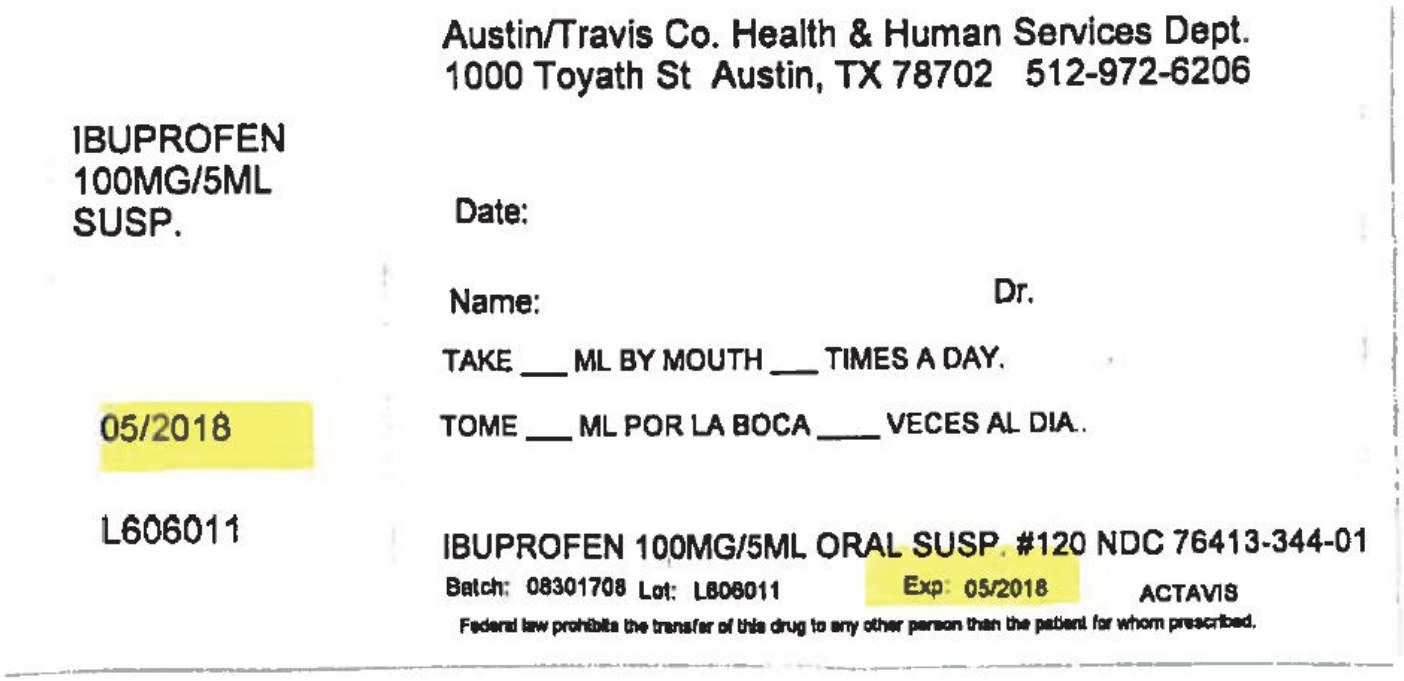
05/2018

L606011

IBUPROFEN 100MG/5ML ORAL SUSP. #120 NDC 76413-344-01

Batch: 08301708
Lot: L606011
Exp: 05/2018
ACTAVIS

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.



CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76413-344(NDC:0472-1255)
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	ORANGE (red)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-344-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074916	06/01/2006	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-344) , RELABEL(76413-344)

Revised: 9/2017 Central Texas Community Health Centers