

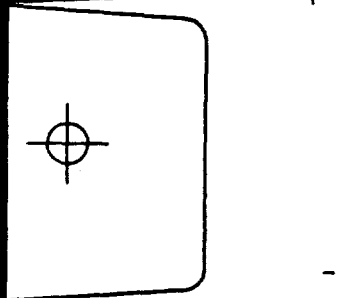
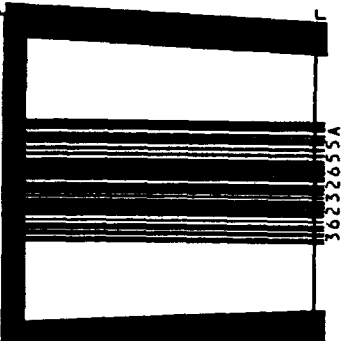
**CENTER FOR DRUG EVALUATION AND
RESEARCH
74-937**

APPLICATION NUMBER:

APPROVED DRAFT LABELING

Final Printed Labeling
 Ibuprofen Oral Suspension
 100 mg/5 mL
 ANDA 74-937
 4 oz. Carton

Y55923293



Ibuprofen Oral Suspension
 Fever Reducer/Pain Reliever
 Child-Resistant Safety Cap
 Unbreakable Bottle

Mylan# 839

WARNING:
ASPIRIN SENSITIVE CHILDRN:
 • This product contains no aspirin, but may cause a severe reaction in people allergic to aspirin.
 • Do not use this product if your child has had an allergic reaction to aspirin such as skin rash, swelling, chest or throat.

CALL YOUR DOCTOR IF:
 • Your child is under a doctor's care for any serious condition or is taking any other drug.
 • Your child has problems or serious side effects from taking fever reducers or pain relievers.
 • Your child does not get any relief within 48 hours (24 hours) of treatment, or pain or fever gets worse.
 • Redness or swelling is present in the painful area.
 • Sores throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea or vomiting.
 • Any new symptoms appear.

DO NOT USE:
 • With any other product that contains ibuprofen, or any other pain reliever/fever reducer, unless directed by a doctor.
 • For more than 3 days for fever or pain unless directed by a doctor.
 • For stomach pain unless directed by a doctor.
 • If your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea or lack of fluid intake.

IMPORTANT:
 • Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.
 • If stomach upset occurs while taking this product, give with food or milk. If stomach upset gets worse or lasts, call your doctor.

ACTIVE INGREDIENT: Ibuprofen.

Inactive Ingredients (aqueous): Butylparaben, Citric Acid, Carn. Syrup, Flav. Glycine, Hydroxypropyl Methylcellulose, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Xanthan Gum, DDC Red #33, FD&C Yellow #6, FD&C Red #40.

Ibuprofen Oral Suspension

Fever Reducer/Pain Reliever

IMPORTANT: Read all product information before using. Keep this box for important information. This product is intended for use by children only.

USES:
 For temporary relief of:
 • Fever
 • Minor aches and pains due to colds, flu, sore throat, headaches and toothaches

DIRECTIONS:
 1. Find right dose on chart below. If possible, use weight to dose; otherwise use age.
 2. Measure dose with cup provided.
 3. Repeat dose every 4-6 hours, if needed.
 4. Do not use more than 4 times a day.

SHAKE WELL BEFORE USING

WEIGHT (lb)	AGE (yr)	DOSE (approximately)
Under 24	Under 2	Consult Doctor
24-35	2-3	1 tsp
36-47	4-5	1½ tsp
48-59	6-8	2 tsp
60-71	9-10	2½ tsp
72-95	11	3 tsp

One Dose Lasts 8-8 Hours

Ibuprofen Oral Suspension

Fever Reducer/Pain Reliever

NEW

LASTS UP TO 8 HOURS

BERRY-FLAVORED LIQUID

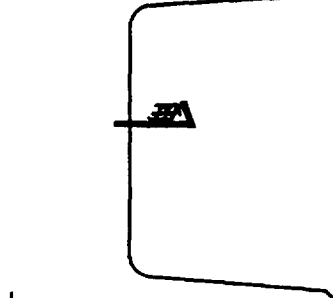
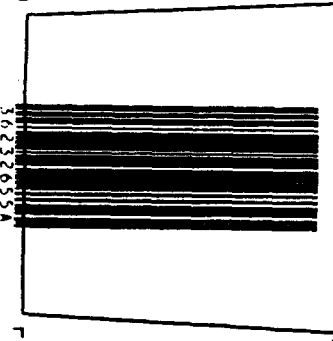
Ibuprofen Oral Suspension

• Long Lasting: Up to 8 hours of fever and pain relief.
 • Great Convenience: Long duration means fewer doses needed per day.
 • Berry-Flavored Liquid: Specially developed for children.

Questions? Ask your Pharmacist, Doctor or Health Care Professional.

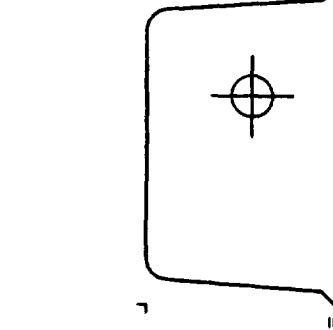
See bottom of box for lot number and expiration date.
 Store at room temperature: 15°-30°C (59°-86°F)

MANUFACTURED BY
PERRIGO
 ALLEBAUM, IN 46000 U.S.A.



LOT NO.
 0 700301 50334 5

EXP.
 1 823 28 55 A



{Lot number and expiration date will appear on carton.}

under paragraph (2)(B)(I) is received." You have notified FDA that L. Perrigo Company (Perrigo) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Perrigo within the statutory forty-five day period.

Please provide the Agency, at least 60 days prior to the expiration of the applicable exclusivity protection (June 16, 1998), an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. If not previously notified by OGD, you should specifically request that a determination be made concerning the 180-day exclusivity provisions as they may relate to this application. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above. Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter, or delay in issuance of the final approval letter.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under 21 U.S.C. 355. The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

Prior to submitting the amendment, please contact Mr. James Wilson, III, Project Manager, at (301) 827-5848 for further instructions.

Sincerely yours,

 9/5/97

Roger L. Williams, M.D.

Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research