

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

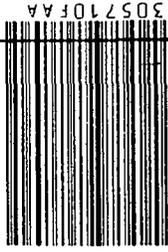
75-217

APPLICATION NUMBER:

APPROVED DRAFT LABELING

Final Printed Labeling
 Ibuprofen Oral Suspension, 50 mg/1.25mL
 ANDA 75-217
 1 ounce carton

**Mylar
 EFB339**



Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 2-3 years.

Active Ingredient: Ibuprofen.

Uses: Temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches.

Directions:

1. Shake well before using.
2. Find right dose on chart below. If possible, use weight to dose; otherwise use age.
3. Only use enclosed dropper; fill to prescribed level and dispense liquid slowly into child's mouth, toward inner cheek.
4. Replace original bottle cap to maintain child resistance.
5. If needed, repeat dose every 6-8 hours.
6. Do not use more than 4 times a day.
7. If stomach upset occurs while taking this product, give with food or milk.

Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2.5 mL)

One Dose Lasts 6-8 Hours

Attention: Specially designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing device.

Warnings

Allergic Reactions: This product may cause a severe allergic reaction which may include:
 -wheezing (asthma) -shortness of breath
 -hives -swelling of the face
 -fast, irregular pulse or heartbeat
 -changing color of the skin (shock)

Aspirin-Sensitive Patients: Although this product does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people allergic to aspirin or other pain relievers/fever reducers. Any of these reactions could be serious. Stop using this product and get emergency medical help immediately. These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to this product or other pain relievers/fever reducers.

(See Side Panel to the Right for Additional Warnings) /

Warnings (continued)

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 first day (24 hours) of treatment, or pain or fever gets worse.
- Stomach upset gets worse or lasts.
- Redness or swelling is present in the painful area.
- Sore 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.
- DO NOT USE IF PRINTED NECK-BAND IS BROKEN OR MISSING.

Important:

- Do not exceed recommended dose. Taking more than the recommended dose (overdose) may not provide more relief and could cause serious health problems.

(See Opposite Side Panel for Additional Warnings) /

CONCENTRATED ORAL DROPS
Ibuprofen
Oral Suspension

**Fever Reducer
 Pain Reliever**

Child-Resistant Safety Cap
 Read Instructions Carefully

NEW

**For Ages 2-3
 CONCENTRATED ORAL DROPS**

Ibuprofen
Oral
Suspension

**Fever Reducer
 Pain Reliever**

Lasts up to 8 hours.



BERRY-FLAVORED

Warnings (continued)

- Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Questions? If you have questions of a medical nature, please contact your Pharmacist, Doctor or Health Care Professional.

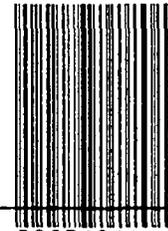
See bottom of box for lot number and expiration date.

Store at room temperature: 15°-30°C (59°-86°F).

Inactive Ingredients: Butylparaben, Citric Acid, FD&C Red #40, Artificial Flavor, Glycerin, Hydroxypropyl Methylcellulose, Polysorbate 80, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Sucrose, and Xanthan Gum.



MANUFACTURED BY
PERRIGO
 ALLEGAN, MI 49010 U.S.A.



305710FAA

LOT NO.

EXP.

3 057 10 FA A

DEC 16 1998

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

Final Printed Labeling
 Ibuprofen Oral Suspension, 50mg/1.25mL
 ANDA 75-217
 1/2 ounce label

Warnings: Allergic Reactions: This product may cause a severe allergic reaction which may include: wheezing, rash/hives, shortness of breath, throat swelling that may obstruct breathing, dizziness, swelling of the face, lips, tongue, or throat, or changes in voice. **Severe Skin Reactions:** Although the product does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people allergic to aspirin or other pain relievers/fever reducers. Any of these reactions could be serious. Stop using this product and get emergency medical help immediately. These reactions can occur after taking a single dose or any subsequent doses. Stop using this product and get emergency medical help immediately. Stop using this product if you experience any of the following symptoms: hives, itching, skin rash, facial swelling, or other allergic reactions. **Important:** See box for complete WARNINGS and other information and take for full use.

Uses: Temporarily reduces fever and relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches.

Directions: 1. Shake well before using. 2. Read right side on the chart below. If possible, use weight to dose.

For Ages 2-3
CONCENTRATED ORAL SUSPENSION
Ibuprofen
Oral
Suspension

Fever Reducer & Pain Reliever

50 mg/1.25 mL
 1.25 FL OZ (37.5 mL)

otherwise use age. 3. Only use enclosed dropper. 4. Do not prescribe or dispense to children under 2 years of age. 5. Do not use more than 4 doses a day. 6. Do not use more than 4 doses a day. 7. If stomach upset occurs while taking this product, give well with food.

Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2.5 mL)

Store at room temperature (20°-25°C, 68°-77°F). Contains 0.050% alcohol.

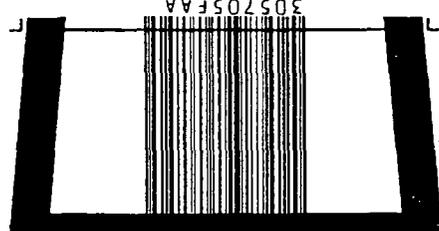
LOT: 05740515A
 EXP: 05/15/18

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

marzo

Final Printed Labeling
Ibuprofen Oral Suspension, 50mg/1.25mL
ANDA 75-217
1/2 ounce carton

Mylar #
311



Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 2-3 years.
Active Ingredient: Ibuprofen.
Uses: Temporarity:
-relieves fever
-relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches.
Directions:
1. Shake well before using.
2. Find right dose on chart below. If possible, use weight to dose; otherwise use age.
3. Only use enclosed dropper; fill to prescribed level and dispense liquid slowly into child's mouth, toward inner cheek.
4. Replace original bottle cap to maintain child resistance.
5. If needed, repeat dose every 6-8 hours.
6. Do not use more than 4 times a day.
7. If stomach upset occurs while taking this product, give with food or milk.

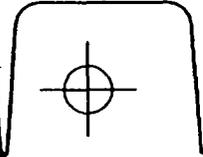
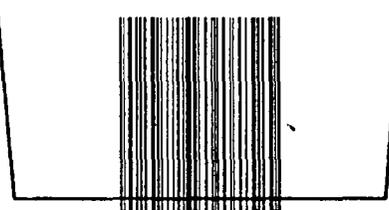
Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2.5 mL)

One Dose Lasts 6-8 Hours

Attention: Specially designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing device.

Warnings
Allergic Reactions: This product may cause a severe allergic reaction which may include:
-wheezing(asthma) -shortness of breath
-hives -swelling of the face
-fast, irregular pulse or heartbeat
-changing color of the skin (shock)
Aspirin-Sensitive Patients: Although this product does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people allergic to aspirin or other pain relievers/fever reducers. Any of these reactions could be serious. Stop using this product and get emergency medical help immediately. These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to this product or other pain relievers/fever reducers.

(See Side Panel to the Right for Additional Warnings) /



Warnings (continued)
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 first day (24 hours) of treatment, or pain or fever gets worse.
• Stomach upset gets worse or lasts.
• Redness or swelling is present in the painful area.
• Sore 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.
• DO NOT USE IF PRINTED NECK-BAND IS BROKEN OR MISSING.
Important:
• Do not exceed recommended dose. Taking more than the recommended dose (overdose) may not provide more relief and could cause serious health problems.
(See Opposite Side Panel for Additional Warnings) /

CONCENTRATED ORAL DROPS
Ibuprofen
Oral Suspension
Fever Reducer
Pain Reliever
Child-Resistant Safety Cap
Read Instructions Carefully

NEW For Ages 2-3
CONCENTRATED ORAL DROPS
Ibuprofen
Oral
Suspension

Fever Reducer
Pain Reliever
Lasts up to 8 hours



BERRY-FLAVORED

APPROVED
LOT NO. **DEC 16 1998**
EXP. **DEC 16 1998**
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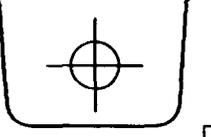
Warnings (continued)
• Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Questions? If you have questions of a medical nature, please contact 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).

Inactive Ingredients: Butylparaben, Citric Acid, FD&C Red #40, Artificial Flavor, Glycerin, Hydroxypropyl Methylcellulose, Polysorbate 80, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Sucrose, and Xanthan Gum.



MANUFACTURED BY
PERRIGO
ALLEGAN, MI 48801 U.S.A.



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

Final Printed Labeling
 Ibuprofen Oral Suspension, 50mg/1.25mL
 ANDA 75-217
 1 ounce label

Warnings-Allergic Reactions: This product may cause a severe allergic reaction which may include: wheezing (asthma), shortness of breath, fever, swelling of the face, feet, irregular pulse or heartbeat, or changing color of the skin (shock).

Aspirin Sensitive Patients: Although this product does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people allergic to aspirin or other pain relievers/fever reducers. Any of these reactions could be life-threatening. Stop using this product and get emergency medical help immediately. These reactions can occur after taking a single dose or any subsequent dose in persons both with and without prior reaction to this product or other pain relievers/fever reducers.

Important: See box for complete WARNINGS and other information and save for future use.

Uses: Temporarily reduces fever and relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches.

Directions: 1. Shake well before using. 2. Find right dose on the chart below. If possible, use weight to dose, otherwise use age. 3. Only use enclosed dropper; fill to prescribed level and

For Ages 2-3
CONCENTRATED ORAL DROPS
Ibuprofen
Oral
Suspension

Fever Reducer
Pain Reliever

ORAL SUSPENSION
 PREPARED BY PERRIGO PHARMACEUTICALS

dispense liquid slowly into child's mouth, toward inner cheek. 4. Replace original bottle cap to maintain child resistance. 5. If needed, repeat dose every 6-8 hours. 6. Do not use more than 4 times a day. 7. If stomach upset occurs while taking this product, give with food or milk.

Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Droppers (2.5 mL)

Store at room temperature 15°-30°C (59°-86°F).
 Contains 0.009% alcohol.

MANUFACTURED BY
PERRIGO
 ALLIANCE W. MICHIGAN, U.S.A.

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