CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-603/S-001, S-002, S-003

APPROVED LABELING
ASPIRIN SENSITIVE CHILDREN:
Although this product does not contain aspirin, it may cause a severe reaction in people allergic to aspirin. Children's Motrin may cause: asthma, hives, shock (low blood pressure), allergy, shortness of breath or swelling of the face. Children's Motrin can cause serious reactions, similar to those listed above, requiring immediate medical attention. These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to Children's Motrin or other pain reliever/fever reducer. DO NOT USE: If plastic bottle wrap imprinted with "Safety Seal®" is broken.

For Ages 2–3

Children's Motrin® Drops

IMPORTANT: See box for complete WARNINGS and other information and save box for future use. USES: For Temporary: Reduction of fever and relief of 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 dropper provided. Use enclosed dropper only. 3. Repeat dose every 6–8 hours, if needed. 4. Do not use more than 4 times a day. Store at 15°–30°C (59°–86°F). SHARE WELL.

<table>
<thead>
<tr>
<th>Age</th>
<th>Under 6</th>
<th>Over 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>24–35</td>
<td>2–3</td>
<td>2 Dropperfuls (2x1.25 mL)</td>
</tr>
</tbody>
</table>

Control: Exp. Date: 00000000 00000000

CHILDREN'S MOTRIN SUSP DROPS . LABEL
Children's Motrin Drops

For Ages 2–3

Important: See back for complete WARN
INGS and other information and uses less for
children under 2. USES: For Temporary Reducing
of fever and relief of 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
determine dose; otherwise use age. 2. Measure
dose with dropper provided. Use enclosed dropper
only. 3. Repeat does every 4–6 hours, if need
ed. 4. Do not use more than 4 times a day.
Store at 15°C–30°C (59°F–86°F). SHAKE WELL.

<table>
<thead>
<tr>
<th>Age</th>
<th>Under 2</th>
<th>Under 2</th>
<th>Consult Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24–35</td>
<td>2–3</td>
<td>2 Dropperfuls</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(2 x 1.25 mL)</td>
</tr>
</tbody>
</table>
# Motrin® Concentrated Drops

**For Ages 2-3**

**Ibuprofen Oral Suspension**

**Soda Flavor Drops**

**BENEFITS**
- Reduces fever
- Relieves minor aches/pains due to colds, flu, minor pain, headache

**DIRECTIONS**

1. Shake well before using.
2. Find right dose on chart below. If possible, use weight to determine 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's resistance.
5. If needed, repeat dose every 4-6 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.

**Dosage Chart**

<table>
<thead>
<tr>
<th>AGE</th>
<th>DROPPERFULS</th>
<th>2 Dropperfuls (2 x 1.25 ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 24</td>
<td>2 - 3</td>
<td>2 Dropperfuls (2 x 1.25 ml)</td>
</tr>
</tbody>
</table>

**Important**

- Do not exceed recommended dose. Taking more than the recommended dose (overdose) may not provide more relief and may cause serious health problems. Keep this and all dropper out of the reach of children. In case of accidental overdose, seek professional assistance or contact your poison control center immediately.

**Side Effects**

- Redness or swelling 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

**Other Ingredients**

- Citric acid, sodium benzoate, sorbitol, sucrose, xanthan gum

**Questions or Comments?**

Call toll free 1-800-962-5357

Or ask your pharmacist.

**Storage**

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

**Inactive Ingredients**

- Propylene glycol, water, sodium benzoate, sorbitol, sucrose, xanthan gum

**Manufactured by**

Mann's Consumer Products Co.

Division of Mann's, Inc.

2220 Southlawn Drive

Princeton, PA 19070 USA

© 1996

U.S. Patent No. 5,374,659

**Expiration**

000000-0000 00

000000-0000 00
200% ENLARGED

WARNINGs: Allergic Reactions: Children's Motrin may cause a severe allergic reaction which may include: wheezing (asthma), shortness of breath, hives, swelling of the face, fast, irregular pulse or heartbeat, or changes in color of the skin (shock). ASPIRIN-SENSITIVE PATIENTS: Although Children's Motrin 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 should be reported. 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 Children's Motrin or other pain relievers/fever reducers. IMPORTANT: See last for complete WARNINGS and other information and save last for future use. U.S.A. FDA Temporary: Reduction of fever and relief of minor aches and pains due to colds, 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 4-8 hours. 6. Do not use more than 4 doses a day. 7. If stomach upset occurs while taking this product, give with food or milk. Store at room temperature: 15°-30°C (59°-86°F).

Weight (lbs) | Age (yr) | Dose
--- | --- | ---
Under 24 | Under 2 | Consult Doctor
24-35 | 2-3 | 2 Dropperfuls (12 x 125 mL)
## Children's Motrin Concentrated Drops

**WARNINGS**: ALLERGIC REACTIONS: Children's Motrin may cause a severe allergic reaction which may include: wheezing (twitching); shortness of breath; hives; swelling of the face, lips, tongue, or pharynx; or hives of the skin (shock). ASPIRIN-SENSITIVE PATIENTS: Although Children’s Motrin 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 a prior reaction to Children’s Motrin or other pain relievers/fever reducers. IMPORTANT: See box for complete WARNINGS and other information and save box for future use. DS: For Temporary Relief of fever and relief of minor aches and pains due to colds, flu, sore throat, headaches and toothaches. DIRECTIONS: 1. Shake well before using. 2. Find right dose on chart below. 3. Possible, use weight to dose, otherwise use age. 4. Only use enclosed dropper to prescribed level and disperse liquid slowly into child's mouth, toward inner cheek. 4. Replace original bottle cap to maintain child resistance. 5. If needed, repeat dose every 4-6 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. Store at room temperature: 15°C to 30°C (59°F to 86°F).

<table>
<thead>
<tr>
<th>Weight (lb)</th>
<th>Age (yr)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 24</td>
<td>Under 2</td>
<td>Consult Doctor</td>
</tr>
<tr>
<td>24 - 35</td>
<td>2 - 3</td>
<td>2 Dropperfuls (2x1/2 mL)</td>
</tr>
</tbody>
</table>
Principal Display Panel-carton

Infants' Motrin
CONCENTRATED
Drops
For ages 6 months to 23 months

IBUPROFEN ORAL SUSPENSION
50 mg per 1.25 mL (dropperful)
Fever Reducer/Pain Reliever
Lasts up to 8 hours
Use Only With Enclosed Dropper
See New Label

BERRY-FLAVORED DROPS
Alcohol Free
1/2 FL OZ (15 mL)

Back Panel
Important: Read all product information before using. Keep this box for important information.
This product is intended for use in children ages 6 months to 23 months of age.

Drug Facts

Active ingredient (in each 1.25 mL) Purpose
Ibuprofen 50 mg........................................Fever reducer/pain reliever

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

Drug Facts (continued)

Warnings
Allergy alert: ibuprofen may cause a severe allergic reaction which may include:
- hives
- facial swelling
- asthma (wheezing)
- shock

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 pain reliever/fever reducer

Ask a doctor before use if the child has
- not been drinking fluids
- lost a lot of fluid due to continued vomiting or diarrhea
- stomach pain
- problems or serious side effects from taking fever reducers or pain relievers
Ask a doctor or pharmacist before use if the child is
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer

When using this product give with food or milk if stomach upset occurs

Stop use and ask a doctor if
- an allergic reaction occurs. Seek medical help right away.
- fever or pain gets worse or lasts more than 3 days
- the child does not get any relief within first day (24 hours) of treatment
- stomach pain or upset gets worse or lasts
- 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.

Directions
- do not give more than directed
- shake well before using
- find the right dose on chart below. If possible, use weight to dose; otherwise use age.
- use only with enclosed dropper. Fill to dose level. Do not use any other dosing device.
- dispense liquid slowly into the child's mouth, toward inner cheek
- replace original bottle cap to maintain child resistance
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day

Dosing Chart

<table>
<thead>
<tr>
<th>Weight (lb)</th>
<th>Age (mos)</th>
<th>Dose (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 6 mos</td>
<td>call a doctor</td>
<td></td>
</tr>
<tr>
<td>12 - 17 lbs</td>
<td>6-11 mos</td>
<td>1 dropperful (1.25 mL)</td>
</tr>
<tr>
<td>18 - 23 lbs</td>
<td>12-23 mos</td>
<td>1 ½ dropperfuls (1.875 mL)</td>
</tr>
</tbody>
</table>

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

Other information store at 20-25°C (68-77°F)

Inactive ingredients artificial flavors, citric acid, corn starch, FD&C Red #40, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum

Questions or Comments?
Call toll-free 1-800-962-5355
Or ask your Pharmacist, Doctor or Health Care Professional
See bottom of box for lot number and expiration date

McNeil Consumer Healthcare
DIVISION OF McNeil-PPC, Inc.
FORT WASHINGTON, PA 19034 USA
U.S. Patent No. 5,374,659