

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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

APPROVED LABELING

JUN 12 1998

APPROVED

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

ACTIVE INGREDIENT: Ibuprofen.

USES: For Temporary:

- Reduction of fever
- 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.

SHAKE WELL BEFORE USING

Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2 x 1.25 mL)

WARNINGS

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
- shock (low blood pressure)
- shortness of breath
- hives
- allergy
- 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.

(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.
- 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.
- If plastic bottle wrap imprinted with "Safety Seal®" is broken.

See Opposite Side Panel for Additional Warnings) →

Children's Motrin® Drops

IBUPROFEN ORAL SUSPENSION
Fever Reducer/Pain Reliever
Child Resistant Safety Cap

For Ages 2-3

Children's Motrin® Drops

IBUPROFEN ORAL SUSPENSION
80 mg Per 1.25 mL (Dropperful)
Fever Reducer/Pain Reliever

Lasts up to 8 hours



BERRY-FLAVORED DROPS



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WARNINGS (CONTINUED)

IMPORTANT:

- 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.
- If stomach upset occurs while taking this product, give with food or milk. If stomach upset gets worse or lasts, call your doctor.

Questions or Comments?
Call toll free
1-800-962-5357

Or 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)

Inactive Ingredients: Citric acid, cornstarch, artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum, FD&C Red #40.

McNEIL

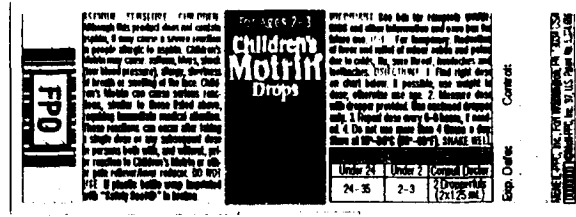
McNEIL Consumer Products Co
Division of McNEIL-PPC, Inc.
Fort Washington, PA 19004 USA
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U.S. Patent No. 5,374,659

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	<p>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.</p>	<p>For Ages 2-3</p> <h1 style="margin: 0;">Children's Motrin®</h1> <h2 style="margin: 0;">Drops</h2>	<p>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). SHAKE WELL.</p>	<p>Control:</p> <p>Exp. Date:</p>	<p>McNEIL-PPC, Inc., Fort Washington, PA 19034 USA ©McNeil-PPC, Inc. '57 U.S. Patent No. 3,374,659 000000001</p>	
	<table border="1"> <thead> <tr> <th>Under 24</th> <th>Under 2</th> <th>Consult Doctor</th> </tr> </thead> <tbody> <tr> <td>24-35</td> <td>2-3</td> <td>2 Dropperfuls (2x1.25 mL)</td> </tr> </tbody> </table>	Under 24	Under 2			Consult Doctor
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24-35	2-3	2 Dropperfuls (2x1.25 mL)				

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

ACTIVE INGREDIENT: Ibuprofen.

USES: For Temporary:

- Reduction of fever
- 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.

SHAKE WELL BEFORE USING

Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2 x 1.25 mL)

WARNINGS

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
- shock (low blood pressure)
- shortness of breath
- hives
- allergy
- 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.

(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.
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- 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.
- If plastic bottle wrap imprinted with "Safety Seal®" is broken.

See Opposite Side Panel for Additional Warnings! →

Children's
Motrin
Drops

IBUPROFEN ORAL SUSPENSION
Fever Reducer/Pain Reliever

For Ages 2-3

Children's
Motrin
Drops

IBUPROFEN ORAL SUSPENSION
60 mg per 1.25 mL (dropperful)

Fever Reducer/Pain Reliever

Lasts up to 8 hours



BERRY FLAVORED DROPS



EXP:

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WARNINGS (continued)

IMPORTANT:

- Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance, 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.

Questions or Comments?
Call toll free
1-800-962-5357

Or 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)

Inactive Ingredients: Citric acid, cornstarch, artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum, FD&C Red #40.

McNELL

McNELL Consumer Products Co.
Division of McNELL-PPC, Inc.
Fort Washington, PA 19034 USA
Child-PPC, Inc. 97
U.S. Patent No. 5,374,859



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FPO	<p>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 impunctured with "Safety Seal" is broken.</p>	<p>For Ages 2-3 Children's Motrin[®] Drops</p>	<p>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 (50°-86°F). SHARE WELL!</p>						
			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center;">Under 24</td> <td style="width: 33%; text-align: center;">Under 2</td> <td style="width: 33%; text-align: center;">Consult Doctor</td> </tr> <tr> <td style="text-align: center;">24-35</td> <td style="text-align: center;">2-3</td> <td style="text-align: center;">2 Dropperfuls (2x1.25 mL)</td> </tr> </table>	Under 24	Under 2	Consult Doctor	24-35	2-3	2 Dropperfuls (2x1.25 mL)
Under 24	Under 2	Consult Doctor							
24-35	2-3	2 Dropperfuls (2x1.25 mL)							
			<p>Exp. Date: _____ Control: _____</p> <p style="font-size: small; text-align: right;">MCHL-PPC, Inc., Fort Washington, PA 19034 USA 0000000000 GMAH-PPC, Inc. 97, U.S. Patent No. 5,374,659</p>						

SEP 13 1999

APPROVED



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

ACTIVE INGREDIENT: Ibuprofen.

USES: For Temporary:

- Reduction of fever
- 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 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 x 1.25 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: 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
- changing 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 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 Children's Motrin or other pain relievers/fever reducers.

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

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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.
- If plastic bottle wrap imprinted "Safety Seal®" and "Use With Enclosed Dropper Only" is broken or missing.

(See Opposite Side Panel for Additional Warnings) →

Children's Motrin®
CONCENTRATED
Drops
IBUPROFEN ORAL SUSPENSION
Read Instructions Carefully Child-Resistant Safety Cap



For Ages 2-3

Children's Motrin®
CONCENTRATED
Drops
IBUPROFEN ORAL SUSPENSION
50 mg per 1.25 ml (400 mg/30 ml)
Fever Reducer/Pain Reliever

Lasts up to 8 hours

See New Label



Use Only With Enclosed Dropper

BERRY-FLAVORED DROPS



EXP:

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WARNINGS (continued)

IMPORTANT:

Do not exceed recommended dose. Taking more than the recommended dose (overdose) may not provide more relief and could cause serious health problems. **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 or Comments?
Call toll free
1-800-962-5357
Or ask your Pharmacist,
Doctor or other 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: Citric acid, cornstarch, FD&C Red #40, artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum.

McNEIL
McNEIL CONSUMER PRODUCTS CO.
DIVISION OF McNEIL-PPC, INC.
FORT WASHINGTON, PA 19034 USA
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U.S. Patent No. 5,374,659

Labeling: _____
NDA No: _____
Rec'd: _____
S002

SEP 15 1999

AMERICAN
PHARMACEUTICALS



Children's Motrin[®] CONCENTRATED Drops

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 changing 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 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 Children's Motrin or other pain relievers/fever reducers. **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. 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. Store at room temperature: 15°-30° C (59°-86° F).

Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2x125 mL)

Exp. Date: _____
Control: _____

MGHEIL-PPC, INC., FORT WASHINGTON, PA 19034 USA
0000000001 ©McH-PPC, Inc. '98, U.S. Patent No. 5,374,659

Labeling: _____
NDA No.: _____
Reviewed by: _____
Rec'd: _____



Children's Motrin[®] CONCENTRATED Drops

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 changing 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 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 Children's Motrin or other pain relievers/fever reducers. **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. 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. Store at room temperature: 15°-30° C (59°-86° F).

Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2x125 mL)

Exp. Date: _____
Control: _____
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0000000001 ©McH-PPC, Inc. '98, U.S. Patent No. 5,374,659

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

ACTIVE INGREDIENT: Ibuprofen.

USES: For Temporary:

- Reduction of fever
- 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 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 (kg)	AGE (yr)	DOSE
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2 x 1 25 mL)

One Dose lasts 6-8 hours

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

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
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(See Side Panel to the Right for Additional Warnings)

WARNINGS (continued)

CALL YOUR DOCTOR IF:

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DO NOT USE:

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- 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.
- If plastic bottle wrap imprinted "Safety Seal" and "Use With Enclosed Dropper Only" is broken or missing.

(See Opposite Side Panel for Additional Warnings)

Children's Motrin[®] CONCENTRATED Drops

IBUPROFEN ORAL SUSPENSION

Read Instructions Carefully Child-Resistant Safety Cap

For Ages 2-3

Children's Motrin[®] CONCENTRATED Drops

IBUPROFEN ORAL SUSPENSION

50 mg per 1.25 mL (SUSPENSION)

Fever Reducer/Pain Reliever

Lasts up to 8 hours

See New Label



Use Only With Enclosed Dropper

BERRY-FLAVORED DROPS

FPO



EXP:

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WARNINGS (continued)

IMPORTANT!

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

Call toll free 1-800-962-5357

Or ask your Pharmacist, Doctor or other Health Care Professional.

See bottom of box for lot number and expiration date. Store at room temperature: 15-30 C (50-86 F)

Inactive Ingredients: Citric acid, cornstarch, FD&C Red #40, artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum.

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McNEIL CONSUMER PRODUCTS CO.
DIVISION OF McNEIL-PPC, INC.
FORT WASHINGTON, PA 19034 USA
©McN-PPC, Inc '98
U.S. Patent No. 5,374,659



00000000

Labeling: _____
NDA No: _____
Reviewed by: _____

SEP 13 1998

APPROVED

SEP 13 1989

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Children's Motrin[®] CONCENTRATED Drops

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 changing 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 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 Children's Motrin or other pain relievers/fever reducers. **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. 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. Store at room temperature: 15°-30°C (59°-86°F).

Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2x1.25 mL)

Exp. Date:

Control:

MICHEL-PPC, INC., FORT WASHINGTON, PA 19034 USA
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Children's Motrin[®] CONCENTRATED Drops

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Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2x1.25 mL)

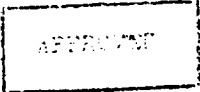
Exp. Date:

Control:

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APR 15 1993

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)

Purposes

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

Weight (lb)	Age (mos)	Dose (mL)
Under 6 mos		call a doctor
12 - 17 lbs	6-11 mos	1 dropperful (1.25 mL)
18 - 23 lbs	12-23 mos	1 ½ dropperfuls (1.875 mL)

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 1-800-962-5357

Or ask your Pharmacist, Doctor or Health Care Professional
See bottom of box for lot number and expiration date

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