

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-128

FINAL DRAFT PRINTED LABELING

Prototype Labeling

A. CARTON

TOP PANEL:

Do not use if plastic carton wrap or bottle wrap imprinted "Safety Seal®" is broken or missing.

Children's
MOTRIN®
Cold
Berry
Flavor

PRINCIPAL DISPLAY PANEL:

NDC xxxxx-xxx-xx

Children's
MOTRIN®
Cold
Ibuprofen /pseudoephedrine HCl oral suspension
100 mg/15 mg per 5 mL (teaspoonful)

Pain Reliever/Fever Reducer
Nasal Decongestant

Lasts up to 6 hours
• Fever • Stuffy nose
• Sore throat

Graphic (adult administering to child)
Flag: *NEW*

Berry
flavor

Alcohol Free

1 fl oz (30) mL (or
4 fl oz (120 mL))

BOTTOM PANEL:

UPC
Lot:
Exp.

BACK LEFT AND RIGHT SIDE PANELS:

Drug Facts	
Active ingredients (in each 5 mL teaspoon)	Purpose
Ibuprofen 100 mg.....	Pain reliever/ fever reducer
Pseudoephedrine HCl 15 mg.....	Nasal decongestant
Uses temporarily relieves these cold, sinus, and flu symptoms:	
• nasal and sinus congestion • minor body aches and pains • fever • stuffy nose • headache • sore throat	
Warnings	
Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: • hives • asthma (wheezing) • facial swelling • shock	
Sore throat warning: severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.	
Do not use	
• if the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant • in a child who is taking a prescription monoamine oxidase inhibitor [MAOI] (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.	
Ask a doctor before use if the child has	
• not been drinking fluids • lost a lot of fluid due to continued vomiting or diarrhea • problems or serious side effects from taking pain relievers, fever reducers or nasal decongestants • stomach pain • heart disease • thyroid disease • high blood pressure • diabetes	
Ask a doctor or pharmacist before use if the child is	
• under a doctor's care for any continuing medical condition • taking any other drug • taking any other product that contains ibuprofen or pseudoephedrine • taking any other pain reliever fever reducer and/or nasal decongestant	
When using this product	
• do not exceed recommended dosage • 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. • the child does not get any relief within first day (24 hours) of treatment • fever, pain or nasal congestion gets worse, or lasts for more than 3 days • stomach pain or upset gets worse or lasts • symptoms continue or get worse • redness or swelling is present in the painful area • the child gets nervous, dizzy, sleepless or sleepy • 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 right dose on chart below. If possible, use weight to dose; otherwise use age.
- only use enclosed measuring cup
- if needed, repeat dose every 6 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance

Dosing chart

Weight (lb)	Age (yrs)	Dose
under 24	under 2	Ask a doctor
24 – 47	2 to 5	1 tsp.
48 – 95	6 to 11	2 tsp.

Other information

- do not use if plastic carton wrap or bottle wrap imprinted "Safety Seal®" is broken or missing
- store at 20°-25°C (68°-77°F)
- see bottom of box for lot number and expiration date

Inactive ingredients acesulfame potassium, citric acid, corn starch, D&C yellow #10, FD&C red #40, flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

Questions or Comments? Call toll-free 1-800-862-5357

{The sponsor should follow this DRUG FACTS label in content only. The font sizes for title, headings, subheadings, condensed text and other graphic features must be in accordance as set forth in 21CFR201.66.}

B: IMMEDIATE CONTAINER LABEL:

Do not use if plastic bottle wrap imprinted "Safety Seal®" is broken or missing

NDC xxxxx-xxx-xx

**Children's
MOTRIN®**

Cold

Ibuprofen and pseudoephedrine HCl Oral Suspension
100mg/15 mg per 5 mL (teaspoonful)

**Pain Reliever/Fever Reducer
Nasal Decongestant**

Lasts up to 6 hours

**Lot #XXXXXX
Exp. Date XXXXXXXX**

**MCNEIL-PPC INC, FORT WASHINGTON, PA 19034 USA
©MCN-PPC, Inc. '00**

Active ingredients (in each 5 mL teaspoon)**Purposes**

Ibuprofen 100 mg..... Pain reliever/fever reducer
Pseudoephedrine HCl 15 mg..... Nasal decongestant

Uses temporarily relieves these cold, sinus, and flu symptoms:

- nasal and sinus congestion - • stuffy nose
- minor body aches and pains • headache
- fever • sore throat

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 a doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

Do not use

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant

Stop use and ask a doctor if • an allergic reaction occurs. Seek medical help right away

Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.

Directions

- do not use more than directed
- shake well before using
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- only use enclosed measuring cup
- if needed, repeat dose every 6 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance

Dosing chart

Weight (lb)	Age (yrs)	Dose
under 24	under 2	Ask a doctor
24 - 47	2 to 5	1 tsp.
48 to 95	6 to 11	2 tsp.

Other information

- store at 20°-25°C (68°-77°F)
- see side edge of label for lot number and expiration date

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Drug Facts (continued)

Do not use if the child has ever had an allergic reaction to any other 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
 • problems or serious side effects from taking fever reducers or pain relievers
 • heart disease
 • high blood pressure
 • thyroid disease
 • diabetes
 • stomach pain

Ask a doctor or pharmacist before use if the child is:
 • under a doctor's care for any serious condition
 • taking any other drug
 • using any other product that contains ibuprofen, or any other pain reliever/fever reducer

When using this product, do not exceed recommended dosage. 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 for 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 pants area.
 • the child gets nervous, dizzy or sleepless.
 • 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.

Drug Facts (continued)

Directions: Do not give more than directed. Shake well before using. Find right dose on chart below if possible. Use weight to dose, otherwise use age. Only use enclosed measuring cup. 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.

Weight (lb)	Age (yr)	Dose (teaspoon)
under 24	under 2	call a doctor
24 to 35	2 to 3	1 tsp
36 to 47	4 to 5	1 1/2 tsp
48 to 59	6 to 8	2 tsp
60 to 71	9 to 10	2 1/2 tsp
72 to 95	11	3 tsp

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

Other information

Do not use if plastic carton wrap or bottle were imprinted "Safety Seal" is broken or missing. Store at 20-25°C (68-77°F). See bottom of box for lot number and expiration date.

Inactive ingredients

saccharine potassium, citric acid, corn starch, D&C yellow #10, FD&C red #40, flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum.

Children's Motrin Cold

Berry flavor

FPO

00000000

Children's Motrin Cold

Fever • Stuffy nose • Sore throat



Berry flavor
Alcohol Free

Important: Read all product information before using. Keep this box for important information. This product is for children only.

Drug Facts

Active ingredients **Purposes**
 (in each 5mL teaspoon)
 ibuprofen 100 mg ... Fever reducer/pain reliever
 pseudoephedrine ... Nasal decongestant
 - 15 mg

Use temporarily. Reduces fever. Relieves symptoms associated with the common cold, flu, sinusitis including nasal and sinus congestion. Stuffy nose, headache, sore throat, body aches and pains.

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 in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, emotional conditions or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving the product.

Drug Facts (continued)

Questions or comments?
 Call toll-free 1-800-852-5567 Or ask your Pharmacist, Doctor or Health Care Professional

Bested Consumer Products
 DIVISION OF MCNEIL - PPC, INC.
 FORT WASHINGTON, PA 19044 USA
 BULKHEAD, INC. 90

EXP

EXP

LOT

Labeling Format Information: (modified)

Fonts: Helvetica regular, bold and bold italic.

Drug Facts: 8.25 pt
 Header: 7 pt
 Subheader: 6 pt
 Body Text: 6 pt
 Drug Facts (continued): 7 pt

Leading: 6 pt
 Bullets: 5 pt
 Barlines: 2.5 pt
 Hairlines: 0.5 pt

Horizontal Scale: 80-85%

Average Kerning: -30



Children's Motrin® Cold

Berry Flavor

Important: Read all product information before using. Keep the box for important information. This product is for children only. **Uses** temporarily: reduces fever, relieves symptoms associated with the common cold, flu or sinusitis including: nasal and sinus congestion, stuffy nose, headache, sore throat, body aches and pains.

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock. Do not use if the child has ever had an allergic reaction to any other pain reliever/fever reducer. **Directions** • do not give more than directed • shake well before using • find right dose on chart below • 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 Use only enclosed measuring cup to dose this product. Do not use any other dosing device. Do not use if bottle wrap is broken or missing.

Weight (lb)	under 24	24 to 35	36 to 47	48 to 59	60 to 71	72 to 95
Age (yr)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11
Dose (tsp)	call a doctor	1 tsp	1 1/2 tsp	2 tsp	2 1/2 tsp	3 tsp

EXP LOT

EXP Date:
 Lot:
 10000000

MCNEIL - PPC, INC., FORT WASHINGTON, PA 19004 USA © MCN-PPC, Inc. '00
 Store at 20-25°C (68-77°F)

200% OF SIZE



Children's Motrin® Cold

Berry Flavor

Important: Read all product information before using. Keep the box for important information. This product is for children only. **Uses** temporarily: reduces fever, relieves symptoms associated with the common cold, flu or sinusitis including: nasal and sinus congestion, stuffy nose, headache, sore throat, body aches and pains.

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock. Do not use if the child has ever had an allergic reaction to any other pain reliever/fever reducer. **Directions** • do not give more than directed • shake well before using • find right dose on chart below • 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 Use only enclosed measuring cup to dose this product. Do not use any other dosing device. Do not use if bottle wrap is broken or missing.

Weight (lb)	under 24	24 to 35	36 to 47	48 to 59	60 to 71	72 to 95
Age (yr)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11
Dose (tsp)	call a doctor	1 tsp	1 1/2 tsp	2 tsp	2 1/2 tsp	3 tsp

EXP LOT

EXP Date:
 Lot:
 10000000

MCNEIL - PPC, INC., FORT WASHINGTON, PA 19004 USA © MCN-PPC, Inc. '00
 Store at 20-25°C (68-77°F)

Labeling Format Information: (modified)

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	0 pt	Leading:	4-4.5 pt
Header:	4.5 pt	Bullets:	4.5 pt
Subheader:	4.5 pt	Barlines:	0 pt
Body Text:	4.5 pt	Hairlines:	0 pt
Drug Facts (continued): NA			

Horizontal Scale: 70-73%

Average Kerning: -20

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Children's Motrin Cold

Berry
flavor



Drug Facts (continued)

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:

- do not exceed recommended dosage
- 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 for 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
- the child gets nervous, dizzy or sleepless
- 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 right dose on chart below. If possible, use weight to dose; otherwise use age.
- only use enclosed measuring cup
- 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

Weight: (lb)	Age (yr)	Dose (teaspoon)
under 24	under 2	call a doctor
24 to 35	2 to 3	1 tsp
36 to 47	4 to 5	1 1/2 tsp
48 to 59	6 to 8	2 tsp
60 to 71	9 to 10	2 1/2 tsp
72 to 95	11	3 tsp

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

Children's Motrin Cold

Fever Reducer/Pain Reliever
Nasal Decongestant

Berry
flavor

Drug Facts (continued)

Other information

- do not use if plastic carton wrap or bottle wrap imprinted "Safety Seal" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of box for lot number and expiration date

Inactive Ingredients

accesulfate potassium, citric acid, corn starch, D&C yellow #10, FD&C red #40, flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

Questions or comments?

Call toll-free 1-800-862-5357
Or ask your Pharmacist, Doctor or Health Care Professional

Mckel Consumer Healthcare
DIVISION OF MCKEL - PPC, INC.
EIGHT WASHINGTON, PA 16014 USA ©MCKEL-PPC, Inc. '90

Children's Motrin Cold

Fever Reducer/Pain Reliever
Nasal Decongestant

• Fever • Stuffy nose
• Sore throat



Berry
flavor
Alcohol Free

Important: Read all product information before using. Keep this box for important information. This product is for children only.

Drug Facts

Active ingredients Purposes (in each 5mL teaspoon)

Ibuprofen 100 mg.....Fever reducer/pain reliever
Pseudoephedrine HCl 15 mg.....Nasal decongestant

Uses temporarily:

- reduces fever
- relieves symptoms associated with the common cold, flu or sinusitis including:
- nasal and sinus congestion
- stuffy nose
- headache
- sore throat
- body aches and pains

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 in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, emotional conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Do not use if the child has ever had an allergic reaction to any other 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
- problems or serious side effects from taking fever reducers or pain relievers
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- stomach pain

FPO

0000-0000-000

EXP

Labeling Format Information:

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	9 pt	Leading:	6.5 pt
Header:	8 pt	Bullets:	5 pt
Subheader:	6 pt	Barlines:	2.5 pt
Body Text:	6 pt	Hairlines:	0.5 pt
Drug Facts (continued):	6 pt		

Horizontal Scale: 90-100%

Average Kerning: -10

Important: Read all product information before using. Keep the box for important information. This product is for children only.

Drug Facts

Active ingredients (in each 5mL teaspoon)

Ibuprofen 100 mg.....Fever reducer/pain reliever
Pseudoephedrine HCl 15 mg.....Nasal decongestant

Purposes

Uses temporarily:

- reduces fever
- relieves symptoms associated with the common cold, flu or sinusitis including:
 - nasal and sinus congestion
 - stuffy nose
 - headache
 - sore throat
 - body aches and pains

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 other pain reliever/fever reducer.

Children's Motrin Cold

Ibuprofen and pseudoephedrine oral suspension

Fever Reducer/Pain Reliever
Nasal Decongestant

Berry flavor

Stop use and ask a doctor if ■ an allergic reaction occurs.
Seek medical help right away.

Directions ■ do not give more than directed ■ shake well before using ■ find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ only use enclosed measuring cup ■ 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

Weight (lb)	Age (yr)	Dose (teaspoon)
under 24	under 2	call a doctor
24 to 35	2 to 3	1 tsp
36 to 47	4 to 5	1 1/2 tsp
48 to 59	6 to 8	2 tsp
60 to 71	9 to 10	2 1/2 tsp
72 to 95	11	3 tsp

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

Other information

■ store at 20-25°C (68-77°F)

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MONEL - PPC, INC., FORT WASHINGTON, PA 19034 USA
© MON-PPC, Inc. '00

150% OF SIZE

Important: Read all product information before using. Keep the box for important information. This product is for children only.

Drug Facts

Active ingredients
(in each 5mL teaspoon)

Ibuprofen 100 mg.....Fever reducer/pain reliever
Pseudoephedrine HCl 15 mg.....Nasal decongestant

Purposes

Uses temporarily:

- reduces fever
- relieves symptoms associated with the common cold, flu or sinusitis including:
 - nasal and sinus congestion
 - stuffy nose
 - headache
 - sore throat
 - body aches and pains

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 other pain reliever/fever reducer.

Children's Motrin Cold

Ibuprofen and pseudoephedrine oral suspension

Fever Reducer/Pain Reliever
Nasal Decongestant

Berry flavor

Stop use and ask a doctor if ■ an allergic reaction occurs.
Seek medical help right away.

Directions ■ do not give more than directed ■ shake well before using ■ find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ only use enclosed measuring cup ■ 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

Weight (lb)	Age (yr)	Dose (teaspoon)
under 24	under 2	call a doctor
24 to 35	2 to 3	1 tsp
36 to 47	4 to 5	1 1/2 tsp
48 to 59	6 to 8	2 tsp
60 to 71	9 to 10	2 1/2 tsp
72 to 95	11	3 tsp

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

Other information

■ store at 20-25°C (68-77°F)

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Labeling Format Information: (modified)

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	5.5 pt	Leading:	4.5 pt
Header:	5.5 pt	Bullets:	3.5 pt
Subheader:	4.5 pt	Barlines:	1.5 pt
Body Text:	4.5 pt	Hairlines:	0.5 pt
Drug Facts (continued): NA			

Horizontal Scale: 82-90%

Average Kerning: -20

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Drug Facts (continued)

Do not use if the child has ever had an allergic reaction to any other pain reliever/fever reducer.

Ask a doctor before use if the child has:
 • not been drinking fluids
 • not a lot of fluid due to continued vomiting or diarrhea
 • problems or serious side effects from taking fever reducers or pain relievers
 • heart disease
 • high blood pressure
 • thyroid disease
 • diabetes
 • stomach pain

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 do not exceed recommended dosage.
 • 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 for 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.
 • the child gets nervous, dizzy or sleepless.
 • 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.

Drug Facts (continued)

Directions: Do not give more than directed. Shake well before using. Find right dose on chart below if possible. Use weight to dose, otherwise use age. Only use enclosed measuring cup. 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.

Weight (lb)	Age (yr)	Dose (teaspoon)
under 24	under 2	call a doctor
24 to 35	2 to 3	1 tsp
36 to 47	4 to 5	1 1/2 tsp
48 to 59	6 to 8	2 tsp
60 to 71	9 to 10	2 1/2 tsp
72 to 95	11	3 tsp

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

Other information

Do not use if plastic carton wrap or bottle wrap imprinted "Safety Seal" is broken or missing. Store at 20-25°C (68-77°F). See bottom of box for lot number and expiration date.

Inactive ingredients

acetylsalicylic potassium, citric acid, corn starch, D&C red #33, FD&C blue #1, FD&C red #40, flavors, glycerin, polyorbene 80, purified water, sodium benzoate, sucrose, xanthan gum.

Children's Motrin Cold

Children's Motrin Cold

Fever • Stuffy nose
• Sore throat



Grape
flavor
Alcohol free

Important: Read all product information before using. Keep this box for important information. This product is for children only.

Drug Facts**Active ingredients**

(in each 5mL teaspoon)
 ibuprofen 100 mg. Fever reducer/pain reliever
 pseudoephedrine
 15 mg. Nasal decongestant

Uses temporarily:
 • reduces fever
 • relieves symptoms associated with the common cold, flu, or sinusitis including:
 • nasal and sinus congestion
 • stuffy nose
 • headache
 • sore throat
 • body aches and pains

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 in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (antidepressants for depression, psychiatric, emotional conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Drug Facts (continued)**Questions or comments?**

Call toll-free 1-800-852-5367 or ask your Pharmacist, Doctor or Health Care Professional.

James C. Scherer
 DIVISION OF SCHERER - PPC, INC.
 PORT WASHINGTON, PA 19084 USA
 © 1998 PPC, INC.

EXP. LOT

Labeling Format Information: (modified)

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	8.25 pt	Leading:	6 pt
Header:	7 pt	Bullets:	5 pt
Subheader:	6 pt	Barlines:	2.5 pt
Body Text:	6 pt	Hairlines:	0.5 pt
Drug Facts (continued):	7 pt		

Horizontal Scale: 80-85%

Average Kerning: -30



Children's Motrin®

Cold

Grape Flavor

Important: Read all product information before using. Keep the box for important information. This product is for children only. **Uses temporarily:** reduces fever, relieves symptoms associated with the common cold, flu or sinusitis including: nasal and sinus congestion, stuffy nose, headache, sore throat, body aches and pains.

Warnings: Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock. Do not use if the child has ever had an allergic reaction to any other pain reliever/fever reducer. **Directions:** • do not give more than directed • shake well before using • find right dose on chart below • 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. Use only enclosed measuring cup to dose this product. Do not use any other dosing device. Do not use if bottle wrap imprinted "Safety Seal®" is broken or missing.

Weight (lb)	under 24	24 to 35	36 to 47	48 to 59	60 to 71	72 to 95
Age (yr)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11
Dose (tsp)	call a doctor	1 tsp	1 1/2 tsp	2 tsp	2 1/2 tsp	3 tsp

EXP LOT

EXP Date:
 Mfg:
 10000000

MICREL - PFC, INC. FORT WASHINGTON, PA 19034 USA © MCN-PFC, Inc. '00
Store at 20-25°C (68-77°F)

200% OF SIZE



Children's Motrin®

Cold

Grape Flavor

Important: Read all product information before using. Keep the box for important information. This product is for children only. **Uses temporarily:** reduces fever, relieves symptoms associated with the common cold, flu or sinusitis including: nasal and sinus congestion, stuffy nose, headache, sore throat, body aches and pains.

Warnings: Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock. Do not use if the child has ever had an allergic reaction to any other pain reliever/fever reducer. **Directions:** • do not give more than directed • shake well before using • find right dose on chart below • 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. Use only enclosed measuring cup to dose this product. Do not use any other dosing device. Do not use if bottle wrap imprinted "Safety Seal®" is broken or missing.

Weight (lb)	under 24	24 to 35	36 to 47	48 to 59	60 to 71	72 to 95
Age (yr)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11
Dose (tsp)	call a doctor	1 tsp	1 1/2 tsp	2 tsp	2 1/2 tsp	3 tsp

EXP LOT

EXP Date:
 Mfg:
 10000000

MICREL - PFC, INC. FORT WASHINGTON, PA 19034 USA © MCN-PFC, Inc. '00
Store at 20-25°C (68-77°F)

Labeling Format Information: (modified)			
Fonts: Helvetica regular, bold and bold italic.			
Drug Facts:	0 pt	Leading:	4-4.5 pt
Header:	4.5 pt	Bullets:	4.5 pt
Subheader:	4.5 pt	Barlines:	0 pt
Body Text:	4.5 pt	Hairlines:	0 pt
Drug Facts (continued): NA			
Horizontal Scale: 70-73%		Average Kerning: -20	

Children's Motrin Cold

Grape flavor



Drug Facts (continued)

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

- do not exceed recommended dosage
- 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 for 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
- the child gets nervous, dizzy or sleepless
- 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 right dose on chart below. If possible, use weight to dose; otherwise use age.
- only use enclosed measuring cup
- replace original bottle cap to maintain child resistance
- if needed, repeat dose every 5-8 hours
- do not use more than 4 times a day

Weight (lb)	Age (yr)	Dose (teaspoon)
under 24	under 2	call a doctor
24 to 35	2 to 3	1 tap
36 to 47	4 to 5	1 1/2 tap
48 to 59	6 to 8	2 tap
60 to 71	9 to 10	2 1/2 tap
72 to 95	11	3 tap

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

Children's Motrin

Cold

Fever Reducer/Pain Reliever
Nasal Decongestant

Grape flavor

Drug Facts (continued)

Other information

- do not use if plastic carton wrap or bottle wrap imprinted "Safety Seal" is broken or missing
- store at 20-25°C (68-77°F)
- see bottom of box for lot number and expiration date

Inactive ingredients

acesulfame potassium, citric acid, corn starch, D&C red #33, FD&C blue #1, FD&C red #40, flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sucrose, xanthan gum

Questions or comments?

Call toll-free 1-800-862-5357
Or ask your Pharmacist, Doctor or Health Care Professional

McNeil Consumer Healthcare
DIVISION OF MCNEIL-PPC, INC.
EAST WILMINGTON, DE 19811 USA

Children's Motrin

Cold

Fever Reducer/Pain Reliever
Nasal Decongestant

• Fever • Stuffy nose
• Sore throat



Grape flavor
Alcohol Free

Important: Read all product information before using. Keep this box for important information. This product is for children only.

Drug Facts

Active ingredients **Purposes**
(in each 5mL teaspoon)
Ibuprofen 100 mg.....Fever reducer/pain reliever
Pseudoephedrine HCl 15 mg.....Nasal decongestant

Uses temporarily:

- reduces fever
- relieves symptoms associated with the common cold, flu or sinusitis including:
 - nasal and sinus congestion
 - stuffy nose
 - headache
 - sore throat
- body aches and pains

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 in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, emotional conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Do not use if the child has ever had an allergic reaction to any other 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
 - problems or serious side effects from taking fever reducers or pain relievers
 - heart disease
 - high blood pressure
 - thyroid disease
 - diabetes
 - stomach pain



EXP:

Labeling Format Information:

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	9 pt	Leading:	6.5 pt
Header:	8 pt	Bullets:	5 pt
Subheader:	6 pt	Barlines:	2.5 pt
Body Text:	6 pt	Hairlines:	0.5 pt
Drug Facts (continued):	6 pt		

Horizontal Scale: 98-100%

Average Kerning: -10

Important: Read all product information before using. Keep the box for important information. This product is for children only.

Drug Facts

Active ingredients (in each 5mL teaspoon) **Purposes**
 Ibuprofen 100 mg.....Fever reducer/pain reliever
 Pseudoephedrine HCl 15 mg.....Nasal decongestant

Uses temporarily:

• reduces fever
 • relieves symptoms associated with the common cold, flu or sinusitis including:
 • nasal and sinus congestion • stuffy nose
 • headache • sore throat • body aches and pains

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 other pain reliever/fever reducer.

Children's Motrin Cold

Ibuprofen and pseudoephedrine oral suspension

Fever Reducer/Pain Reliever
 Nasal Decongestant

Grape flavor

Stop use and ask a doctor if • an allergic reaction occurs.
 Seek medical help right away.

Directions: • do not give more than directed • shake well before using • find right dose on chart below. If possible, use weight to dose; otherwise use age. • only use enclosed measuring cup • 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

Weight (lb)	Age (yr)	Dose (teaspoon)
under 24	under 2	call a doctor
24 to 35	2 to 3	1 tsp
36 to 47	4 to 5	1 1/2 tsp
48 to 59	6 to 8	2 tsp
60 to 71	9 to 10	2 1/2 tsp
72 to 95	11	3 tsp

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

Other information

Store at 20° - 25°C (68° - 77°F) 00000000

EXP. DATE: 12/10/01
 MCNEIL - PPC, INC., FORT WASHINGTON, PA 19034 USA
 © MCNEIL-PPC, Inc. '00

150% OF SIZE

Important: Read all product information before using. Keep the box for important information. This product is for children only.

Drug Facts

Active ingredients (in each 5mL teaspoon) **Purpose**
 Ibuprofen 100 mg.....Fever reducer/pain reliever
 Pseudoephedrine HCl 15 mg.....Nasal decongestant

Uses temporarily:
 • reduces fever
 • relieves symptoms associated with the common cold, flu or sinusitis including:
 • nasal and sinus congestion • stuffy nose
 • headache • sore throat • body aches and pains

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 other pain reliever/fever reducer.

Children's Motrin Cold

Ibuprofen and pseudoephedrine oral suspension

Fever Reducer/Pain Reliever
 Nasal Decongestant

Grape flavor

Stop use and ask a doctor if • an allergic reaction occurs.
 Seek medical help right away.

Directions: • do not give more than directed • shake well before using • find right dose on chart below. If possible, use weight to dose; otherwise use age. • only use enclosed measuring cup • 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

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72 to 95	11	3 tsp

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

Other information
 Store at 20° - 25°C (68° - 77°F) 00000000

Labeling Format Information: (modified)

Fonts: Helvetica regular, bold and bold italic.

Drug Facts:	5.5 pt	Leading:	4.5 pt
Header:	5.5 pt	Bullets:	3.5 pt
Subheader:	4.5 pt	Barlines:	1.5 pt
Body Text:	4.5 pt	Hairlines:	0.5 pt
Drug Facts (continued):	NA		

Horizontal Scale: 82-90%

Average Kerning: -20