

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:

<i>Drug Facts</i>	
<i>Active ingredients (in each 5 mL teaspoon)</i>	<i>Purpose</i>
Ibuprofen 100 mg.....	Pain reliever/ fever reducer
Pseudoephedrine HCl 15 mg.....	Nasal decongestant
<p><i>Uses</i> temporarily relieves these cold, sinus, and flu symptoms:</p> <ul style="list-style-type: none"> • nasal and sinus congestion • stuffy nose • minor body aches and pains • headache • fever • sore throat 	
<p><i>Warnings</i></p> <p>Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> • hives • facial swelling • asthma (wheezing) • shock <p>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.</p>	
<p>Do not use</p> <ul style="list-style-type: none"> • 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. 	
<p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> • 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 • high blood pressure • thyroid disease • diabetes 	
<p>Ask a doctor or pharmacist before use if the child is</p> <ul style="list-style-type: none"> • 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 	
<p>When using this product</p> <ul style="list-style-type: none"> • do not exceed recommended dosage– • give with food or milk if stomach upset occurs 	
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • 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
- minor body aches and pains
- fever
- stuffy nose
- headache
- sore throat

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

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