

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 |
| <i>Uses</i> temporarily relieves these cold, sinus, and flu symptoms: <ul style="list-style-type: none">• nasal and sinus congestion• stuffy nose• minor body aches and pains• headache• fever• sore throat | |
| <i>Warnings</i> Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: <ul style="list-style-type: none">• 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 <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. | |
| Ask a doctor before use if the child has <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 | |
| Ask a doctor or pharmacist before use if the child is <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 | |
| When using this product <ul style="list-style-type: none">• do not exceed recommended dosage• give with food or milk if stomach upset occurs | |
| Stop use and ask a doctor if <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
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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**
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Other information

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