



Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic				
Drug Facts: 9.00 pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 90%	
Headers: 8.00 pt	Leading: 6.50 pt	Barlines: 2.50 pt		
Subheaders: 6.00 pt	Drug Facts (continued): 8.00 pt	Hairlines: 0.50 pt	Average Tracking: -10	

(b) (4)

Description: Ctn Child Motrin Cold Berry 120mL

File No.: FDA300922

Date: 10/03/2016

Contact: (b) (4)

Submission Artwork

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

Active ingredients (in each 5 mL = 1 teaspoon)

Ibuprofen 100 mg (NSAID)	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 ■ headache ■ sore throat ■ minor body aches and pains ■ fever. **Warnings: Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin reddening ■ rash ■ hives. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if the child: ■ has had stomach ulcers or bleeding problems ■ takes a blood thinning (anticoagulant) or steroid drug ■ takes other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others) ■ takes more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **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 10 days or administer to children under 5 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 and/or nasal decongestant ■ right before or after heart surgery ■ 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.

Do not use if bottle wrap, or foil inner seal imprinted "Safety Seal" is broken or missing.

NDC 50580-902-04

Children's Motrin COLD

contains Ibuprofen (NSAID) Pseudoephedrine HCl

Oral Suspension 100 mg/15 mg per 5 mL (teaspoon)

Pain Reliever/Fever Reducer/Nasal Decongestant

Original Berry Flavor 4 FL OZ (120 mL)

If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product. **Ask a doctor before use if the child has** ■ problems or serious side effects from taking pain relievers, fever reducers, or nasal decongestants ■ stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain ■ ulcers ■ bleeding problems ■ not been drinking fluids ■ lost a lot of fluid due to vomiting or diarrhea ■ high blood pressure ■ heart or kidney disease ■ asthma ■ thyroid disease ■ diabetes ■ taken a diuretic ■ diabetes. **Ask a doctor or pharmacist before use if the child is** ■ taking any other drug containing an NSAID (prescription or nonprescription) and/or pseudoephedrine or any other nasal decongestant ■ taking a blood thinning (anticoagulant) or steroid drug ■ under a doctor's care for any serious condition ■ taking any other drug. **When using this product** ■ **do not exceed recommended dosage** ■ take with food or milk if stomach

upset occurs. **Stop use and ask a doctor if** ■ the child feels faint, vomits blood, or has bloody or black stools. These are signs of stomach bleeding. ■ stomach pain or upset gets worse or lasts ■ child has symptoms of heart problems or stroke. ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ the child does not get any relief within first day (24 hours) of treatment ■ fever, pain, or nasal congestion gets worse or lasts more than 3 days ■ redness or swelling is present in the painful area ■ any new symptoms appear ■ the child gets nervous, dizzy, or sleepless. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) **Directions** ■ **this product does not contain directions or complete warnings for adult use** ■ **do not give more than directed** ■ do not give longer than 10 days, unless directed by a doctor (see Warnings) ■ 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

Weight (lb)	Age (yrs)	Dose (tsp or mL)
under 24	under 2	ask a doctor
24-47	2 to 5	1 tsp or 5 mL
48-95	6 to 11	2 tsp or 10 mL

Other information ■ store between 70-75° F (68-77° F)

Expiry Date: 10/17/2016

Lot: 00000000

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Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic

Drug Facts: NA pt	Body Text: 4.75 pt	Bullets: 3.75 pt	Horizontal Scale: 70%
Headers: 4.75 pt	Leading: 4.80 pt	Barlines: NA pt	
Subheaders: 4.75 pt	Drug Facts (continued): NA pt	Hairlines: NA pt	Average Tracking: -25

McNeil Submission Artwork

Description: Lbl Child Motrin Berry 120mL

File No.: FDA3009922 Version: B-4

Date: 10/03/2016

Contact: (b) (4)

Reference ID: 4079079

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
04/03/2017