

ADVIL FLU & BODY ACHE SUPPLEMENTAL APPLICATION NDA 19-771

Drug Facts	
Active Ingredients (In each caplet)	Purpose
Ibuprofen 200 mg.....	Pain reliever/fever reducer
Pseudoephedrine HCl 30 mg.....	Nasal decongestant
Uses temporarily relieves these symptoms associated with the common cold, sinusitis, or flu <ul style="list-style-type: none"> ■ headache ■ fever ■ nasal congestion ■ minor body aches and pains 	
Warnings	
<p>Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock</p> <p>Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.</p> <p>Do not use if you</p> <ul style="list-style-type: none"> ■ have ever had an allergic reaction to any other pain reliever/fever reducer ■ are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ stomach pain ■ had serious side effects from any pain reliever/fever reducer <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ■ taking any other product that contains ibuprofen or pseudoephedrine ■ taking any other pain reliever/fever reducer or nasal decongestant ■ under a doctor's care for any continuing medical condition ■ taking other drugs on a regular basis <p>When using this product</p> <ul style="list-style-type: none"> ■ do not use more than directed ■ take 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. ■ you get nervous, dizzy, or sleepless ■ nasal decongestion lasts more than 7 days ■ fever lasts for more than 3 days ■ symptoms continue or get worse ■ new or unexpected symptoms occur ■ stomach pain occurs with use of this product or if even mild symptoms persist <p>if pregnant or breast-feeding, ask a health professional before use. It is especially important not to use this product during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<ul style="list-style-type: none"> ■ adults and children 12 years of age and over: <ul style="list-style-type: none"> ■ take 1 caplet every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 caplet, 2 caplets may be used. ■ do not use more than 6 caplets in any 24-hour period unless directed by a doctor ■ the smallest effective dose should be used ■ children under 12 years of age: consult a doctor 	
Other information	
<ul style="list-style-type: none"> ■ store 20 -25°C (68 -77°F). Avoid excessive heat above 40°C (104°F). ■ read all warnings and directions before use. Keep carton. 	
Inactive Ingredients camauba or equivalent wax, croscarmellose sodium, iron oxide, methylparaben, microcrystalline cellulose, propylparaben, silicon dioxide, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, sucrose, titanium dioxide	

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