

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**22-565**

**LABELING**



Blister 10-Count



Carton 20-Count

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

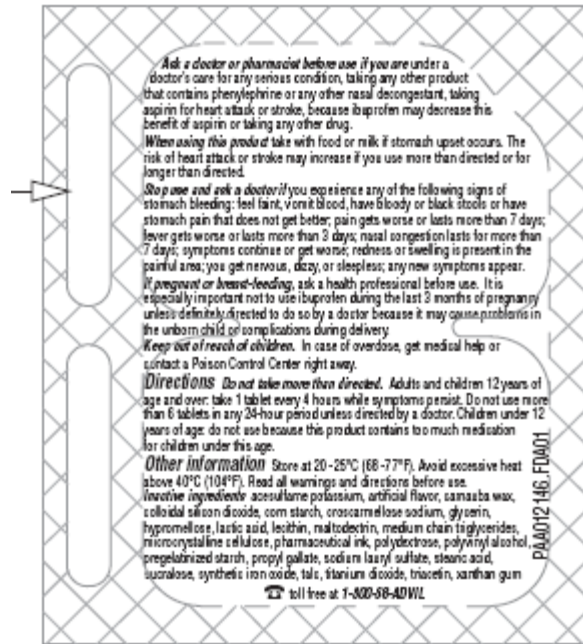
*LET ME READ THIS*

<b>Drug Facts</b> <b>Active ingredients</b> (in each tablet) Ibuprofen 200 mg (NSAID)* Pain reliever/fever reducer Phenylephrine HCl 10 mg..... Nasal decongestant *nonsteroidal anti-inflammatory drug	<b>Purposes</b> Temporarily relieves these symptoms associated with the common cold or flu: ■ headache ■ fever ■ sinus pressure ■ nasal congestion ■ minor body aches and pains ■ reduces swelling of the nasal passages ■ temporarily restores nasal breathing through the nose	<b>Drug Facts (continued)</b> <b>Warnings</b> Always alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheeze) ■ shock ■ skin redness/itching ■ rash ■ blisters If an allergic reaction occurs, stop use and seek medical help right away. <b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older
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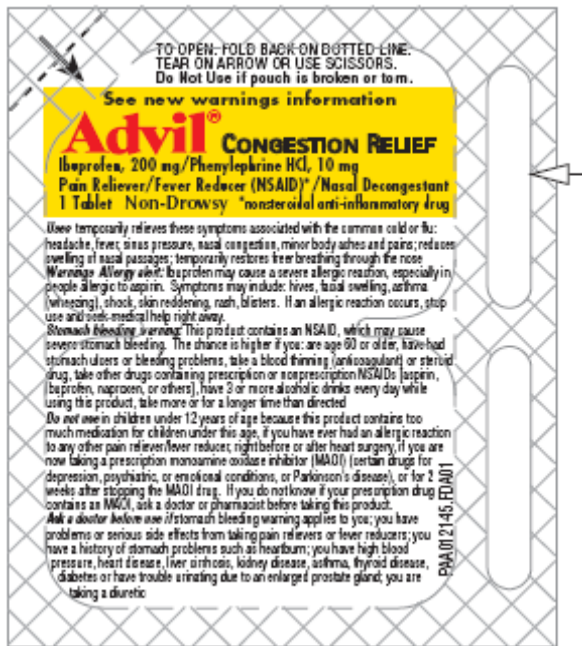
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<b>Drug Facts (continued)</b> ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (naproxen, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed <b>Do not use</b> ■ in children under 12 years of age because this product contains too much medication for children under this age ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, 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) <b>Ask a doctor before use if:</b> ■ stomach bleeding warning applies to you	<b>Drug Facts (continued)</b> ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver disease, kidney disease, asthma, thyroid disease, diabetes or have trouble urinating due to an enlarged prostate gland ■ you are taking a diuretic <b>Ask a doctor or pharmacist before use if you are:</b> ■ under a doctor's care for any serious condition ■ taking any other product that contains phenylephrine or any other nasal decongestant ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin ■ taking any other drug <b>Use with this product:</b> ■ take with food or milk. If stomach upset occurs, the risk of heart attack or stroke may increase if you use more than directed or for longer than directed. <b>May use as directed unless a doctor if:</b> ■ you experience any of the following signs of stomach bleeding: ■ feel faint
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<b>Drug Facts (continued)</b> ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ pain gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ nasal congestion lasts for more than 7 days ■ symptoms continue or get worse ■ redness or swelling is present in the painful area ■ you get numb, dizzy, or dizzy ■ any new symptoms appear If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. <b>Use caution</b> ■ do not take more than directed ■ adults and children 12 years of age and over: ■ take 1 tablet every 4 hours while symptoms persist. ■ do not use more than 6 tablets in any 24-hour period unless directed by a doctor	<b>Drug Facts (continued)</b> ■ children under 12 years of age, do not use because this product contains too much medication for children under this age <b>Other information</b> ■ store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F). ■ read all warnings and directions before use. ■ keep carton. <b>Inactive ingredients</b> salsa flame potassium, artificial flavor, carnauba wax, croscellose, croscellose sodium, gum starch, croscellose sodium, glycerin, hydroxypropylcellulose, lactose, lecithin, malic acid, medium chain triglycerides, microcrystalline cellulose, pharmaceutical ink, polyethylene glycol, pregelatinized starch, polygallic acid, sodium lauryl sulfate, stearic acid, sucralose, synthetic iron oxide, talc, titanium dioxide, triacetin, xanthan gum <b>Directions or comments?</b> ■ If swallowed from 9 AM to 5 PM EST toll free at 1-800-368-0888.
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Pouch Back



FRONT

Pouch Front



Shelf Carton Pouches

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-22565

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ORIG-1

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WYETH  
CONSUMER  
HEALTHCARE

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ADVIL COLD & SINUS  
PE (IBUPROFEN 200MG/PH

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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JOEL SCHIFFENBAUER  
05/27/2010