



Patient Information Leaflet (PIL)

# Advil®

## Cold & Sinus Caplets

**Ibuprofen 200mg / Pseudoephedrine HCl 30mg**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. Serious Warnings and Precautions
2. What Advil® Cold & Sinus Caplets is and what it is used for
3. Before you take Advil® Cold & Sinus Caplets
4. How to take Advil® Cold & Sinus Caplets
5. Possible side effects
6. How to store Advil® Cold & Sinus Caplets
7. Further information

**1. Serious Warnings and Precautions**

- Caution in patients at risk of gastrointestinal tract irritation,
- Patients at risk of kidney problems, including the elderly or those using diuretics.
- Use during pregnancy or nursing should be avoided.
- Stop use immediately if you have difficulty or pain when urinating.

**2. What Advil® Cold & Sinus Caplets is and what it is used for**

Advil® Cold & Sinus contains ibuprofen and pseudoephedrine hydrochloride. Ibuprofen reduces pain and fever, and pseudoephedrine hydrochloride is a nasal decongestant.

Advil® Cold & Sinus caplets is used for fast, temporary relief of the symptoms of colds including sore throat pain, sinus pain, nasal congestion, headache, fever, body aches and pains.

**3. Before you take Advil® Cold & Sinus Caplets**

**Do not take Advil® Cold & Sinus Caplets if you have or you are:**

- allergic/hypersensitive to acetylsalicylic acid (ASA), ibuprofen, other salicylates, other non-steroidal anti-inflammatory drugs (NSAIDs), pseudoephedrine or other sympathomimetic amines or any of Advil® Cold & Sinus' ingredients (Refer to the inactive ingredients section of this insert),
- active or recurrent stomach ulcer or gastrointestinal bleeding or active inflammatory bowel disease (e.g. Crohn's, colitis),
- taking a monoamine oxidase inhibitor (MAOI; e.g. drugs for depression or Parkinson's disease) or for 14 days after stopping the MAOI drug, ASA or other NSAIDs including any other ibuprofen product,
- nasal polyps (swelling of the inside of the nose),
- asthma,
- allergic manifestations such as anaphylaxis (sudden severe life threatening allergic reaction), urticaria/hives, rhinitis (stuffed or runny nose that may be due to allergies), skin rash or other allergic symptoms,
- dehydrated (significant fluid loss) due to vomiting, diarrhea or lack of fluid intake,
- been diagnosed with severe high blood pressure or have heart disease,
- about to have or just had heart surgery,
- serious liver disease,
- severe kidney disease,
- thyroid disease,
- Raynaud's Syndrome (a disorder of the circulatory system),
- Systemic Lupus Erythematosus,
- pregnant or nursing.

**Before you use Advil® Cold & Sinus Caplets talk to your doctor or pharmacist if you have or you are:**

- blood clotting disorder (such as hemophilia)
- breathing problems or chronic lung disease (such as chronic bronchitis)
- diabetes,
- difficulty in urination due to prostate enlargement
- glaucoma
- high blood pressure
- mild to moderate kidney disease
- mild to moderate liver disease
- any other serious disease, are under doctor's care for any serious condition, or are taking any other drug including over the counter drugs.

**Taking Advil® Cold & Sinus Caplets with other medicines, herbal, or dietary supplements**  
**Do not use Advil® Cold & Sinus Caplets if you are taking:**

- a MAOI or if you have stopped taking one within the past two weeks,
- ASA or other anti-inflammatory or pain medication.

**Drugs that may interact with Advil® Cold & Sinus include:**

Acetaminophen, Acetylsalicylic acid (ASA), Allergy medications, Anticoagulants (blood thinning medications), Antidepressants,

Anti-hypertensives (blood pressure medications), Antibiotics (levofloxacin), Benzodiazepines, Cold medications, Corticosteroids, Cyclosporine, Diabetes medication (including insulin and oral antidiabetic agents), Digoxin, Diuretics (water pills), Lithium, Methotrexate, Monoamine Oxidase Inhibitors, Nonsteroidal anti-inflammatory drugs (NSAIDs); including naproxen and ibuprofen, Phenytoin, Probenecid, Thyroxine

- Tell your doctor or pharmacist what prescription or non-prescription drugs you are taking or plan to take.

- Do not smoke or drink alcohol while using this product.

**Pregnancy and Lactation**

Do not use if you are pregnant or nursing a baby.

**4. How to take Advil® Cold & Sinus Caplets**

**Usual dose:**

Adults under 65 years and children over 12: Take 1 or 2 caplets every 4 to 6 hours as needed. Do not exceed six caplets in 24 hours, unless directed by a doctor. Do not give to children under 12. Do not use longer than 3 days for a fever or 5 days for pain or cold symptoms.

**If you take more Advil® Cold & Sinus Caplets than you should**

In case of accidental overdose, discontinue use and seek professional assistance immediately even if there are no symptoms.

**If you forget to take Advil® Cold & Sinus Caplets**

Continue to take 1 or 2 caplets every 4 to 6 hours as needed after a missed dose. Do not take twice the recommended dose following a missed dose.

**5. Possible side effects**

Advil® Cold & Sinus may occasionally produce unwanted side effects, such as heartburn, constipation, nausea, bloating, nervousness or sleeplessness.

Stop use and contact a doctor or pharmacist if these symptoms worsen or persist.

The risk of having side effects may be decreased by using the smallest dose for the shortest duration of time.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM		
Symptoms / Effect	Seek immediate emergency medical assistance	Talk with your doctor or pharmacist (In all cases)
Uncommon	symptoms of allergic reaction including: rash, severe itching/ redness, blisters, swelling, or trouble breathing, blood in vomit, bloody or black stools.	Abdominal pain, vomiting, diarrhea, ringing or buzzing in the ears / dizziness, Change in vision, Fluid retention.

*This is not a complete list of side effects. For any unexpected effects while taking Advil® Cold & Sinus, contact your doctor or pharmacist.*

**6. How to store Advil® Cold & Sinus Caplets**

Store at temperature 15 - 30°C.

Keep out of reach of children. This package contains enough medicine to seriously harm a child.

**7. Further information**

**What Advil® Cold & Sinus Caplets contains**

Each caplet contains:

Active ingredients: Ibuprofen 200mg and Pseudoephedrine HCl 30mg

Inactive ingredients: acetylated monoglycerides, ammonium hydroxide, carnauba wax, cellulose, corn starch, croscarmellose sodium, iron oxides, parabens, pharmaceutical glaze, pharmaceutical shellac, povidone, pregelatinized starch, propylene glycol, silicon dioxide, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, titanium dioxide.

**What Advil® Cold & Sinus Caplets looks like and contents of the pack**

Caplets

Pack sizes: 20's

**Bulk manufactured by:**

Wyeth Pharmaceuticals Company, Guayama, PR, USA.

**Final batch releaser:**

Pfizer Canada Inc., Montreal, Canada.

**Marketing authorization holder:**

Pfizer Consumer Healthcare, Ontario, Canada.

This leaflet was last approved on 06 November 2015

This is a Medication	
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.	
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.	
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.	
- Do not by yourself interrupt the period of treatment prescribed for you.	
- Do not repeat the same prescription without consulting your doctor.	
- Keep all medicaments out of reach of children.	
<b>Council of Arab Health Ministers            Union of Arab Pharmacists</b>	