

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

## **Advil Cold & Sinus 200 mg/30 mg Liqui-Gel capsules**

### **Active ingredients:**

Each Liqui-Gel capsule contains:

Ibuprofen 200 mg (present as the free acid and potassium salt)

Pseudoephedrine HCl 30 mg

For the list of inactive ingredients and allergens in the medicine see section 2, subsection "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Take the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 10 days.

### **1. What is the medicine intended for?**

For the temporary relief of symptoms associated with common cold or flu in the presence of fever or pain accompanied by nasal congestion.

#### **Therapeutic class:**

Ibuprofen belongs to the class of non-steroidal anti-inflammatory drugs (NSAIDs).

Pseudoephedrine belongs to the class of vasoconstrictors (blood vessel constrictors), and acts on the nasal blood vessels to relieve nasal congestion.

### **2. Before using the medicine**

#### **X Do not use Advil Cold & Sinus if:**

- You are sensitive (allergic) to ibuprofen or pseudoephedrine, or to any of the other ingredients the medicine contains, as detailed in section 6, or if you have had an allergic reaction to a similar medicine in the past, such as aspirin/acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). Signs of an allergic reaction include skin rash, hives, itching, breathing difficulties, chest pressure, swelling of the mouth, face, lips or tongue.
- You are under 12 years old.
- You are pregnant or breastfeeding.
- You have a stomach ulcer or stomach bleeding, or any sign of bleeding.
- You have had gastrointestinal problems in the past after taking Advil Cold & Sinus, ibuprofen, aspirin/acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). These problems can include: stomach ulcers, stomach bleeding or perforation.
- You are taking:
  - Other medicines containing non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or aspirin/acetylsalicylic acid.

- Other medicines to clear the nasal passages, taken by mouth or through the nose, such as pseudoephedrine, phenylpropanolamine, phenylephrine or ephedrine.
- Medicines to treat depression from the non-selective monoamine oxidase inhibitors class (MAOIs), such as iproniazid, or if you have taken them in the last 14 days.
- Other medicines to treat depression from the class called tricyclic anti-depressants, such as amitriptyline.
- You have severe cardiovascular diseases that include:
  - Severe heart failure
  - High blood pressure
  - Accelerated heart rate (tachycardia)
  - Angina pectoris
- You have diabetes, overactive thyroid gland or a tumor in the adrenal gland that can cause an increase in blood pressure and heart rate and headaches (pheochromocytoma).
- You have glaucoma (high intra-ocular pressure).
- You have an enlarged prostate gland.
- You have severe liver failure, severe kidney failure or severe heart failure.

**! Special warnings regarding the use of the medicine**

**Before taking this medicine tell the doctor or pharmacist if:**

- You have heart problems including heart failure, angina pectoris (chest pressure), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs and feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischemic attack – TIA), you have high blood pressure, diabetes, high cholesterol, a family history of heart disease or stroke, or if you are a smoker.
- You have asthma – since there is a risk of having an asthma attack.
- You have liver or kidney problems.
- You have problems with your prostate gland.
- You have bleeding problems.
- You have or have had in the past gastrointestinal problems, such as: stomach ulcers, stomach bleeding, ulcerative colitis or Crohn's disease.
- You have lupus erythematosus – a disease affecting the immune system and causing joint pain, skin changes and other problems.
- You have an infection – please see subsection "Infections" in this section.

Pseudoephedrine may cause a positive reaction in drug tests. Do not take this medicine if this affects you.

Decreased blood flow to your optic nerve may occur due to taking Advil Cold & Sinus. If you develop sudden loss of vision or decreased vision, such as a blind spot, stop taking Advil Cold & Sinus and contact your doctor or pharmacist immediately.

If you develop generalized erythema (redness of the skin) accompanied by fever and associated with pustules, stop taking Advil Cold & Sinus and contact your doctor or seek medical attention immediately. See section 4.

Sudden abdominal pain or rectal bleeding may occur with Advil Cold & Sinus, due to inflammation of the colon (ischemic colitis). If you develop these gastrointestinal symptoms, stop taking Advil Cold & Sinus and contact your doctor or seek medical attention immediately. See section 4.

If any of the above conditions applies to you, or if you are not sure, refer to the doctor or pharmacist before taking Advil Cold & Sinus.

**! Heart attack and stroke**

Anti-inflammatory/analgesic medicines like ibuprofen may be associated with a small increase in the risk of heart attack or stroke, particularly when used at high dosages. Do not exceed the recommended dosage or duration of treatment.

**! Infections**

Advil Cold & Sinus may mask signs of infection such as fever and pain. Therefore, Advil Cold & Sinus may delay proper treatment of infections, which may lead to a higher chance of complications. Such cases have been observed in cases of pneumonia caused by a bacterial infection and in cases of bacterial skin infections associated with chickenpox. If you are taking this medicine while you have an infection and the symptoms of the infection persist or worsen, you should seek medical advice immediately.

During an infection associated with chickenpox (varicella), it is recommended to avoid the use of ibuprofen.

**! Skin reactions**

Serious skin reactions have been reported in association with taking this medicine. Stop taking this medicine and seek medical advice immediately if you develop any type of skin rash, lesions in the mucous membranes, blisters, or any other sign of allergy, as these can be the first signs of very serious skin reactions. See section 4.

**! Children and adolescents**

Do not give Advil Cold & Sinus to children under 12 years of age. Talk to your doctor or pharmacist before taking Advil Cold & Sinus if you are 12 to 17 years of age and you have not been drinking fluids or you are dehydrated due to diarrhea or vomiting. There is a higher risk of kidney problems with Advil Cold & Sinus when you are dehydrated.

**! The elderly**

If you are an elderly person taking Advil Cold & Sinus, you are more likely to experience side effects such as stomach bleeding or perforation (signs include abdominal pain and heartburn). These effects may be life threatening. For more information see section 4 "Side effects".

**! Drug interactions**

**If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.** Especially if you are taking:

- Other medicines containing non-steroidal anti-inflammatory drugs (NSAIDs), including cyclooxygenase-2 selective inhibitors for pain relief such as ibuprofen or aspirin/acetysalicylic acid.
- Other medicines to clear the nasal passages, taken by mouth or through the nose, such as pseudoephedrine, phenylpropanolamine, phenylephrine or ephedrine.
- Medicines to treat depression from the non-selective monoamine oxidase inhibitors class (MAOIs), such as iproniazid, or if you have taken them in the last 14 days.
- Other medicines to treat depression from the class called tricyclic anti-depressants, such as amitriptyline.

Do not take Advil Cold & Sinus if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Advil Cold & Sinus.

**Refer to your doctor or pharmacist before taking Advil Cold & Sinus if you are taking any of the following medicines:**

- Medicines to treat depression called reversible inhibitors of monoamine oxidase-A (RIMAs) and selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine
- Linezolid
- Bromocriptine, pergolide, lisuride, cabergoline, ergotamine or dihydroergotamine
- Anticoagulants (i.e., medicines that thin the blood/prevent clotting, such as aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Heparin, used to treat or prevent blood clots
- Lithium, used to treat severe mood problems
- Methotrexate
- Medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol containing medicines, angiotensin II receptor antagonists such as losartan) or any diuretics
- Digoxin or quinidine, used to treat heart problems
- Cyclosporin or tacrolimus, used after a transplant
- Potassium-sparing diuretics such as amiloride or spironolactone
- Phenytoin, used to treat epilepsy
- Probenecid and sulfapyrazone, used to treat gout
- Zidovudine, used to treat HIV
- Medicines from the sulfonylurea group such as gliclazide, used to treat diabetes
- Quinolone antibiotics such as ciprofloxacin
- Ginkgo biloba
- Antacids
- Mifepristone, used for pregnancy termination
- Corticosteroids (type of anti-inflammatory medicines) such as hydrocortisone
- Aminoglycosides such as gentamicin or amikacin
- Furazolidone, an antibacterial agent
- Guanethidine, reserpine or methyl dopa

If you are taking aspirin due to heart attack or stroke, ibuprofen might reduce the efficacy of aspirin.

Tell the doctor you are taking Advil Cold & Sinus if you need to have anesthesia before an operation or medical procedure. The doctor will ask you to stop taking Advil Cold & Sinus a few days before the anesthesia. You should also tell the anesthetist (the doctor who gives you the anesthetic) that you have taken Advil Cold & Sinus.

Other medicines may also affect or be affected by the treatment with Advil Cold & Sinus. Therefore, you should always consult the doctor or pharmacist before taking Advil Cold & Sinus with other medicines.

**! Use of the medicine and alcohol consumption**

Do not drink alcohol during treatment.

**! Pregnancy and breastfeeding**

- Do not take Advil Cold & Sinus if you are pregnant or breastfeeding.
- If you think you might be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.
- This medicine has a possible side effect of kidney impairment in the fetus and deficiency of amniotic fluid starting from the 20th week of pregnancy. It is recommended to avoid using preparations from the NSAIDs family starting from

the 20th week of pregnancy and to consult a healthcare professional if necessary.

**! Fertility**

Ibuprofen may affect a woman's ability to become pregnant. This effect is reversible once treatment with ibuprofen is stopped.

It is unlikely that ibuprofen, when used occasionally, will affect your chances of becoming pregnant. Talk to your doctor before taking this medicine if you have had problems becoming pregnant in the past.

**! Driving and operating machinery**

After taking Advil Cold & Sinus you may feel dizzy or have unusual headaches or problems with your vision or hearing, including seeing or hearing things that are not there (hallucinations). If this happens, do not drive, do not ride a bicycle and do not operate any tools or machinery.

**! Important information about some of the ingredients of the medicine**

Advil Cold & Sinus contains 61.1 mg sorbitol (E-420) per capsule.

Sucrose is a source of fructose. Sorbitol is a source of fructose. If you have been told by your doctor that you (or your child) have an intolerance to certain sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Advil Cold & Sinus contains lecithin from soya. If you are allergic to peanuts or soy, do not use this medicine.

Advil Cold & Sinus contains 0.46 mmol (17.8 mg) potassium per capsule. This should be considered in the case of patients with reduced renal function or patients who require a potassium-restricted diet.

### **3. How should you use the medicine?**

This medicine is intended for short-term use only. You should always take the lowest dosage for the shortest period necessary to relieve your symptoms. Do not use this medicine frequently or for a long period of time without consulting a doctor.

If you have an infection, consult a doctor without delay if symptoms (such as fever or pain) persist or worsen (see section 2).

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

Do not take this medicine for more than 10 days, unless instructed to do so by a doctor.

The generally accepted dosage is:

Adults and children over the age of 12 years:

1 capsule every 4-6 hours, as long as symptoms persist.

If there is no relief in pain or fever when taking one capsule, you may take 2 capsules.

Do not take more than 6 capsules in a 24-hour period.

This medicine is not intended for children under 12 years of age.

**Method of use:**

Do not chew, crush or halve the capsule! No information is available regarding opening the capsule and dispersing its content.

The medicine should be swallowed with a glass of water.

Take this medicine during or after a meal.

**Note:**

Take this medicine with food or milk in cases of heartburn or abdominal pain. If the symptoms are severe, refer to a doctor.

**Do not exceed the recommended dose.**

**If you take more Advil Cold & Sinus than you should:**

Do not continue to take Advil Cold & Sinus if you have accidentally taken more than you should (overdose).

The symptoms may include nausea, abdominal pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and flickering eye movements. The following have been reported in cases of high dosages: drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in the urine, cold body feeling and breathing problems.

If you have taken an overdose of Advil Cold & Sinus, or if a child has accidentally swallowed this medicine, go to a doctor or to a hospital emergency room immediately to get an opinion of the risk and advice on how to proceed. Bring the medicine package which includes the remaining capsules with you to show the doctor.

**If you have forgotten to take Advil Cold & Sinus:**

Do not take a double dose in order to compensate for the dose that you forgot to take.

**Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.**

**If you have any other questions regarding the use of the medicine, refer to the doctor or pharmacist.**

#### **4. Side effects**

As with any medicine, using Advil Cold & Sinus may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The following side effects may occur when taking this medicine:

**Stop taking Advil Cold & Sinus immediately and tell your doctor or pharmacist if you notice any of the following side effects:**

**Common side effects:** may occur in up to one out of 10 people

- Nausea
- Bleeding from the stomach or bowel; signs include vomiting blood, blood in the stool or black stool

**Uncommon side effects:** may occur in up to one out of 100 people

- Severe headaches or headaches that are more painful than usual

**Very rare side effects:** may occur in up to one out of 10,000 people

- Heart attack
- Fast heartbeat or palpitations
- Allergic reaction to Advil Cold & Sinus; signs include skin rash, hives, itching, breathing difficulties, chest pressure, swelling of the mouth, face, lips or tongue
- Blisters on the skin or mucous membranes such as the inside of the mouth; signs include a burning sensation with redness, blisters and ulcers

**Side effects with unknown frequency:** side effects whose frequency has not yet been determined

- Stroke
- Behavioral problems such as a sense of enthusiasm, mental turmoil, anxiety, restlessness or nervousness
- Sudden onset of fever, reddening of the skin or many small pustules (possible symptoms of acute generalized exanthematous pustulosis – AGEP) may occur within the first 2 days of treatment with Advil Cold & Sinus. See section 2
- Inflammation of the colon due to insufficient blood supply (ischemic colitis)
- Reduced blood flow to the optic nerve (ischemic optic neuropathy)

**Additional side effects**

Tell the doctor or pharmacist if you have any of the following side effects:

**Common side effects:** may occur in up to one out of 10 people

- Indigestion, abdominal pain, vomiting, diarrhea, constipation, flatulence

**Uncommon side effects:** may occur in up to one out of 100 people

- Stomach ulcer
- Inability to sleep
- Feeling drowsy or tired
- Feeling dizzy or irritable
- Vision problems
- Headaches that do not go away
- Breakouts on the skin such as rash or itching
- Inflamed stomach or bowel, worsening of inflammatory bowel disease
- Hypersensitivity, such as wheezing and difficulty breathing in patients who have had bronchial asthma (asthma in adults) or allergic disease

**Rare side effects:** may occur in up to one out of 1,000 people

- Kidney problems
- Ringing in the ears (tinnitus)

**Very rare side effects:** may occur in up to one out of 10,000 people

- Depression
- Heart failure
- Kidney failure
- High blood pressure
- Sore or inflamed mouth
- Inflamed pancreas (pancreatitis)
- Narrowing of the intestine
- Aseptic meningitis, worsening of infectious inflammations
- Blood cell problems – you may have an increased tendency for bruises or infections
- Liver problems, including abnormal liver function, liver inflammation (hepatitis) or jaundice (yellowing of the skin or eyes)

**Side effects with unknown frequency:** side effects whose frequency has not yet been determined

- Chest pain
- Dry mouth, a feeling of thirst
- Abnormal spasms, convulsions
- Spinning sensation (vertigo)
- Decreased hematocrit levels and decreased hemoglobin
- Seeing or hearing things that are not there (hallucinations)

- Skin rash, change in skin color to red or purple, fluid retention (edema)
- Decreased frequency of urination, blood or protein in the urine (evident in the results of laboratory tests)
- A severe skin reaction known as DRESS syndrome may occur. The symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

### **Reporting side effects**

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

## **5. How to store the medicine?**

- **Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton and blister. The expiry date refers to the last day of that month.

### **Storage conditions**

Store at a temperature below 25°C. Do not store in a refrigerator.

Do not dispose of this medicine via wastewater or household trash. Consult the pharmacist how to dispose of medicines no longer in use. This will help protect the environment.

## **6. Additional information**

### **In addition to the active ingredients the medicine also contains:**

Polyethylene glycol 600, gelatin, sorbitol sorbitan solution, purified water, potassium hydroxide, D&C yellow no. 10, FD&C red no. 40, fractionated coconut oil, Soya Lecithin blend, ink black Opacode (pharmaceutical ink).

### **What does the medicine look like and what are the contents of the package?**

Advil Cold & Sinus capsules are oval-shaped soft gel capsules filled with a clear liquid. The capsules are light orange to clear light yellow with an orangish tint, imprinted with "Advil C&S" in black ink, and they are packed in a tray.

Each package contains 16 or 32 Liqui-Gel capsules.

Not all package sizes may be marketed.

**Manufacturer:** Fareva Richmond Inc., Virginia, USA for Pfizer, New Jersey, USA.

**Marketing authorization holder:** GSK Consumer Healthcare Israel Ltd., P.O.box 3256, Petach Tikva.

**Registration number of the medicine in the national drug registry of the Ministry of Health:** 135 50 31178 00

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