

# IBUCOLD C 200mg/30mg/300mg Film-Coated Tablet

Oral administration · License No: - · ATC: -

Prescription Only	Analgesic, Antipyretic, Decongestant, Vitamin	Ibuprofen + Pseudoephedrine + Ascorbic Acid
Not for use under 12 years of age		

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**Active ingredient:** Each tablet contains 200 mg ibuprofen, 30 mg pseudoephedrine hydrochloride, and 300 mg ascorbic acid (Vitamin C).

**Excipients:** Calcium hydrogen phosphate (anhydrous), croscarmellose sodium, microcrystalline cellulose (PH101), colloidal silicon dioxide, povidone K30, talc, hydrogenated castor oil, microcrystalline cellulose (ph 112), coating material [Polyvinyl alcohol (E 1203), talc (E553b), quinoline yellow aluminum lake (E 104), titanium dioxide (E171), sunset yellow FCF aluminum lake (E 110), glyceryl monocaprylocaprate, sodium lauryl sulfate]

**Packaging:** Available in blister packs of 10, 20, 24, and 30 tablets.

**IMPORTANT:** Read this **PATIENT INFORMATION LEAFLET** carefully before you start taking this medicine, as it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you personally, do not pass it on to others.

During the use of this medicine, when you visit a doctor or hospital, tell your doctor that you are taking this medicine.

Follow the instructions in this leaflet exactly. Do not use a dose **higher or lower** than the recommended dose for this medicine.

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## What is IBUCOLD C and what is it used for?

IBUCOLD C is an orange oblong, biconvex, unscored film-coated tablet.

IBUCOLD C is a medicine supplied in blister packs of 10, 20, 24, and 30 tablets. IBUCOLD C contains ibuprofen, pseudoephedrine, and ascorbic acid as active ingredients.

Ibuprofen, the active ingredient in IBUCOLD C, is a nonsteroidal anti-inflammatory drug with pain-relieving and fever-reducing properties. Pseudoephedrine is a decongestant that helps relieve congestion in the nose and sinuses (nasal passages).

IBUCOLD C, thanks to its pain-relieving, fever-reducing, and anti-inflammatory effects, is primarily used to treat the conditions listed below:

#### **INDICATION 1**

##### **Flu and common cold**

Treatment of symptoms such as nasal congestion, fever, headache, and mild body aches.

## **Things to consider before using IBUCOLD C**

### **DO NOT use IBUCOLD C in the following situations:**

#### **Cardiovascular Risks**

NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, heart attack, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at higher risk.

IBUCOLD C should not be used for pain treatment before coronary artery bypass graft surgery.

#### **Gastrointestinal Risks**

NSAIDs cause serious adverse effects such as bleeding, ulceration, or perforation of the stomach or intestines, which can be fatal. These adverse effects can occur at any time, with or without warning symptoms. Elderly patients are at higher risk for these serious effects.

If you have hypersensitivity to any of the ingredients in IBUCOLD C,

If you have severe liver disease,

If you have severe acute or chronic kidney disease or kidney failure,

If you have experienced asthma, urticaria, or allergic reactions during treatment with acetylsalicylic acid (Aspirin) or other nonsteroidal anti-inflammatory drugs,

If you have untreated stomach and duodenal ulcers,

If you have inflammatory bowel disease (ulcerative colitis, Crohn's disease),

If you are in the late stages of pregnancy (from the 6th month onwards),

If you are going to undergo or have recently undergone coronary artery bypass surgery,

If you have coronary artery insufficiency (narrowing of the blood vessels supplying the heart),

If your blood pressure is very high (severe hypertension) or if you have hypertension that is not controlled by medication,

If you have cerebral vascular bleeding or other active bleeding,

If you are taking a monoamine oxidase inhibitor for the treatment of depression or mood disorders, or have taken one within the last 14 days,

If you have severe heart failure,

If you are taking any of the following medicines: medicines used to treat depression, atropine used to treat eye or intestinal disorders, alpha or beta blocker-containing blood pressure medicines, blood coagulation medicines, asthma medicines, appetite suppressants, moclobemide used in mood disorders, ergotamine or methysergide used in migraine treatment, oxytocin which causes uterine contractions during childbirth,

If you have kidney stones with aciduria or normal urine pH and oxaluria,

If you have high oxalic acid levels in your urine (hyperoxaluria),

In children under 12 years of age.

**Use IBUCOLD C CAREFULLY in the following situations:**

Your doctor will decide whether you or your child should use IBUCOLD C in the following situations.

Avoid using it with any other medicine from the group of pain, fever, and anti-inflammatory drugs.

If stomach pain occurs, stop using the medicine and consult your doctor.

If you have a history of serious gastrointestinal problems or symptoms, serious bleeding, ulcers, or damage may develop at any point during treatment. Due to possible bleeding, darkening of stool color, blood coming from the mouth, and indigestion symptoms may occur. Therefore, if you have serious gastrointestinal problems such as ulcers, bleeding, and damage, your doctor may recommend starting treatment with the lowest dose and using some protective medicines (misoprostol or proton pump inhibitors) concurrently.

If skin peeling, mucosal damage, or hypersensitivity reactions on the skin are observed, do not continue using IBUCOLD C and consult your doctor as soon as possible.

Use with caution in cases of hypersensitivity such as swelling of the face and throat, difficulty breathing, narrowing of the bronchi (asthma), and rhinitis due to allergy.

If unexplained bruising appears on your body, consult your doctor.

If chills, tremors, sudden high fever, weakness, headache, and vomiting or stiffness in your neck occur, consult your doctor immediately; these could be symptoms of a type of meningitis (aseptic meningitis).

As with other pain, fever, and anti-inflammatory drugs, IBUCOLD C should be used with caution in patients with kidney disease.

As with other pain, fever, and anti-inflammatory drugs, IBUCOLD C may cause elevated values in some liver function tests. Caution should be exercised for signs and symptoms indicating liver dysfunction (nausea, weakness, drowsiness, itching, jaundice, pain in the upper right abdomen, flu-like symptoms).

Since ibuprofen prolongs bleeding time by reducing the aggregation of platelets involved in blood clotting, if you have a clotting disorder, continue IBUCOLD C treatment under medical supervision.

If you develop visual disturbance while using IBUCOLD C, have an eye examination.

Be careful when using IBUCOLD C if you have high blood pressure or heart failure, due to the risk of fluid retention caused by pain, fever, and anti-inflammatory drugs.

If you have heart disease or are at high risk of heart disease (e.g., high blood pressure, diabetes) or high cholesterol, or if you smoke, do not exceed the stated daily dose.

As with other pain, fever, and anti-inflammatory drugs, IBUCOLD C can cause serious side effects such as heart attack or stroke, which may result in hospitalization or death. Although serious cardiovascular events may occur without any warning symptoms, if signs and symptoms such as chest pain, shortness of breath, weakness, difficulty speaking are observed, consult your doctor.

If there is unexplained weight gain or symptoms of edema (swelling in the ankles), consult your doctor.

Do not use for more than 5 days.

Use with caution in patients over 60 years of age.

If you have prostate enlargement and bladder dysfunction, you should use the medicine carefully.

If your thyroid gland is overactive, if you have increased eye pressure, or if you have diabetes, you should use the medicine carefully.

Use with caution in patients with pheochromocytoma (a tumor of the adrenal glands that can cause an increase in adrenaline).

If you have Systemic Lupus Erythematosus (SLE), a connective tissue disease, consult your doctor before use.

Especially in the elderly, the risk of serious side effects such as bleeding and perforation in the gastrointestinal system, which can be fatal, is higher, so it should be used with caution.

If you are an athlete, the doping test may come back positive.

Rarely, sudden onset, severe abdominal pain, nausea, vomiting, and visual disturbance may develop with sympathomimetic drugs, including pseudoephedrine. If these complaints occur, IBUCOLD C treatment should be stopped immediately.

If you have previously been diagnosed with prolonged QT syndrome (a serious heart rhythm disorder that can lead to sudden death) and Torsades de Pointes (a life-threatening irregular heart rhythm) or if these conditions are suspected in you, you should use the medicine carefully.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following the use of pseudoephedrine-containing drugs. PRES and RCVS are rare conditions in which blood flow to the brain is reduced. If symptoms that may indicate PRES or RCVS develop, stop using IBUCOLD C immediately and seek urgent medical attention (for symptoms, see Section "4. What are the possible side effects?").

In diabetic patients, vitamin C use may lead to false results in urine glucose tests.

Since ascorbic acid increases iron absorption, high doses may be dangerous in patients with hemochromatosis, thalassemia, polycythemia, leukemia, or sideroblastic anemia. In cases of iron overload disease, ascorbic acid intake should be kept to a minimum.

Caution should be exercised when ascorbic acid is given to patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, as hemolysis may develop.

High doses of ascorbic acid have been associated with sickle cell crises in patients with sickle cell anemia.

Due to the effect of high-dose ascorbic acid on uric acid excretion, it may cause gouty arthritis in patients.

If these warnings apply to you, even at any time in the past, please consult your doctor.

### **Using IBUCOLD C with food and drink**

No interactions with food and drink have been reported.

### **Pregnancy**

#### **Pregnancy**

*Consult your doctor or pharmacist before using the medicine.*

IBUCOLD C should not be used during pregnancy.

*If you realize you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

### **Breastfeeding**

#### **Breastfeeding**

*Consult your doctor or pharmacist before using the medicine.*

Pseudoephedrine, one of its ingredients, is known to pass into breast milk. The use of IBUCOLD C is not recommended during breastfeeding.

## **Driving and using machines**

### **Driving and using machines**

Do not drive or use machines during IBUCOLD C use as dizziness may occur.

## **Important information about some excipients in IBUCOLD C**

IBUCOLD C contains 30 mg croscarmellose sodium in each film-coated tablet. This should be taken into consideration for patients on a controlled sodium diet.

Hydrogenated castor oil may cause nausea and diarrhea.

IBUCOLD C contains 1.2125 mg sunset yellow (E110) in each tablet. Sunset yellow (E110) may cause allergic reactions.

## **Using with other medicines**

When taken with high blood pressure medications; it may reduce their blood pressure-lowering effects.

May increase the anticoagulant effects of anticoagulants such as warfarin or heparin (medicines that prevent or delay blood clotting).

Concomitant use with other NSAIDs, including COX-2 inhibitors such as aspirin, naproxen, celecoxib, nimesulide, should be avoided as the risk of side effects may increase.

When used with cortisone group medicines, the risk of ulcers and bleeding in the gastrointestinal tract may increase.

Urinary excretion of aminoglycoside antibiotics (e.g., gentamicin, kanamycin, streptomycin) may decrease, and their undesirable effects may increase.

The effect of IBUCOLD C may be delayed when taken with Cholestyramine (a bile acid binding resin).

When used with diuretics (e.g., Furosemide, thiazide), the diuretic effect may decrease, and the risk of kidney dysfunction may increase.

When used with cyclosporine and tacrolimus, immunosuppressants, the risk of kidney dysfunction may increase.

When used with mifepristone (abortion pill), it causes a decrease in the effectiveness of mifepristone.

When used with zidovudine, which is effective against retroviruses including human immunodeficiency virus (HIV), it may increase the risk of blood disorders.

When used with lithium salts (used in mental illnesses), an increase in lithium blood levels and associated side effects may be observed.

When used with quinolone antibiotics (e.g., ciprofloxacin), the risk of severe rhythmic contractions (convulsions) in all or some voluntary muscles may increase.

When used with cardiac glycosides (e.g., digoxin, digitoxin) used in heart failure, they may increase their blood levels by affecting their renal excretion and may cause cardiac arrhythmia.

When used with antiplatelet agents (e.g., aspirin, dipyridamole, clopidogrel) and selective serotonin reuptake inhibitors (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline) used for depression, the risk of gastrointestinal bleeding may increase.

Very rare hypoglycemia (low blood sugar) has been observed when used with sulfonylurea treatment (used in the treatment of diabetes).

Especially with high doses of ibuprofen, when used with drugs that inhibit CYP2C9, an enzyme that metabolizes drugs in the liver (e.g., voriconazole, fluconazole), a reduction in ibuprofen dose should be considered.

Concomitant use of IBUCOLD C with nasal decongestants, tricyclic antidepressants (e.g., amitriptyline, nortriptyline, imipramine, and desipramine), appetite suppressants, and some central nervous system stimulants or MAOIs (monoamine oxidase inhibitors: such as moclobemide) may sometimes cause an increase in blood pressure. Due to the pseudoephedrine content of the drug, it may partially reverse the effect of blood pressure-lowering drugs such as bretylium, bethanidine, guanethidine, debrisoquine, methyldopa, alpha and beta adrenergic blockers. Concomitant use with moclobemide poses a risk of hypertensive crisis (severe blood pressure elevation).

Concomitant use with ergot alkaloids (ergotamine and methysergide; used in migraine treatment) increases the risk of side effects.

Increases the risk of hypertension when used with oxytocin, which is used to facilitate childbirth.

Ibuprofen and other pain, fever, and anti-inflammatory drugs may reduce the effect of drugs used to treat high blood pressure and may increase the risk of kidney damage from ACE inhibitors used to treat high blood pressure.

When used concomitantly, IBUCOLD C may increase the blood levels and unwanted side effects of methotrexate (a drug used in cancer treatment) and antidepressants (used in the treatment of depression).

When used with Ginkgo biloba herbal extract, the risk of gastrointestinal bleeding may increase.

In diabetic patients, ascorbic acid may affect the control of diabetes.

In patients undergoing hemodialysis (blood purification process), it may cause an increase in the plasma levels of oxalic acid, a type of organic acid. Oxalic acid, by accumulating in the body, especially in the kidneys, can play a leading role in the formation of kidney stones.

Since it increases iron absorption, high doses can lead to iron overload (accumulation).

Salicylates reduce active transport across the intestinal wall. Salicylates have been found to reduce ascorbic acid absorption by approximately 1/3. That is, they reduce the effectiveness of ascorbic acid in the body.

Acetylsalicylic acid and barbiturates increase the urinary excretion of ascorbic acid.

Warfarin interacts by reducing the hypoprothrombinemic effect (effect that abnormally lowers prothrombin levels in the circulating blood).

Concomitant administration of ascorbic acid and Vitamin B12 results in inactivation of Vitamin B12.

Concomitant use with aluminum-containing antacids (medicines used to relieve stomach discomfort characterized by high acid secretion) increases aluminum absorption.

Ascorbic acid can interfere with the biochemical determination of glucose, creatinine, and uric acid in blood and urine samples.

In hemodialysis patients, it can cause an increase in plasma oxalic acid levels.

When used with levodopa, it has been reported to reduce levodopa-induced vomiting.

In diabetics, when 500 mg of ascorbic acid was given daily for one week, the blood glucose levels of some controlled diabetics were observed to go out of control.

Ascorbic acid may increase iron excretion when given concomitantly with deferoxamine. Cardiomyopathy (heart muscle disease causing heart failure) and congestive heart failure (heart's inability to pump enough blood to meet the body's needs) have been observed in patients receiving concomitant treatment.

Alcohol may decrease blood ascorbic acid levels.

Chronic or high-dose use of ascorbic acid may inhibit disulfiram-alcohol interaction during concomitant use.

*If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist.*

## How to use IBUCOLD C?

### Instructions for proper use and dose/frequency of administration:

For adults and children over 12 years of age, 2 tablets should be used as an initial dose, and if necessary, 1-2 tablets every 4-6 hours with some water.

No more than 6 tablets should be taken per day unless recommended by a physician.

### Route and method of administration:

IBUCOLD C tablets are taken orally with a glass of water.

### Different age groups:

**Use in children:** IBUCOLD C should not be used in children under 12 years of age. The adult dose is applied to children over 12 years of age.

**Use in the elderly:** The adult dose is applied to the elderly. It should be used with caution in patients over 60 years of age.

### Special use cases:

**Kidney/Liver failure:** IBUCOLD C should be avoided in patients with liver failure or used at a low dose under medical supervision if necessary.

It should not be used in patients with severe acute or chronic kidney disease/kidney failure.

*If you have the impression that the effect of IBUCOLD C is too strong or too weak, talk to your doctor or pharmacist.*

### If you used more IBUCOLD C than you should:

#### If you used more IBUCOLD C than you should

*If you have used more IBUCOLD C than you should, talk to a doctor or pharmacist.*

If you have used more IBUCOLD C than you should, or if children have accidentally used this medicine, always consult a doctor or the nearest hospital for advice on precautions and risk assessment.

Symptoms may include nausea, abdominal pain, vomiting (may have bloody streaks), headache, tinnitus, confusion, and nystagmus. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, seizures (especially in children), weakness and dizziness, blood in the urine, feeling of coldness, breathing problems have been reported.

### If you forget to use IBUCOLD C:

#### If you forget to use IBUCOLD C

*Do not take a double dose to make up for forgotten doses.*

### Effects that may occur when treatment with IBUCOLD C is discontinued:

No adverse effects are expected when IBUCOLD C treatment is discontinued.

## What are the possible side effects?

Like all medicines, IBUCOLD C can cause side effects in people sensitive to its ingredients.

Side effects are listed below according to their frequency:

Very common : May be seen in at least 1 in 10 patients.

Common : May be seen in less than 1 in 10 patients but more than 1 in 100 patients.

Uncommon : May be seen in less than 1 in 100 patients but more than 1 in 1,000 patients.

Rare : May be seen in less than 1 in 1,000 patients but more than 1 in 10,000 patients.

Very rare : May be seen in less than 1 in 10,000 patients.

Unknown : Cannot be estimated from the available data.

**If any of the following occurs, stop using IBUCOLD C and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital:**

Shortness of breath, swelling of the face, lips, eyelids, tongue and throat, severe itching and rash on the skin, palpitations and dizziness due to a drop in blood pressure (hypersensitivity-Allergy)

These are all very serious side effects.

If you have any of these, it means you have a serious allergy to IBUCOLD C. You may need urgent medical intervention or hospitalization.

#### Common

Nervousness

Insomnia

Headache

Dizziness

Drowsiness

Dry mouth

Nausea

Vomiting

Indigestion (Dyspepsia)

Diarrhea

Abdominal pain

Intestinal gas (Flatulence)

Constipation

Blackish dark, sticky, and foul-smelling stool (Melena)

Upper gastrointestinal bleeding (Hematemesis)

Gastrointestinal hemorrhage

Rash

## Uncommon

Rhinitis

Hypersensitivity

Anxiety

Agitation

Tingling (Paresthesia)

Somnolence

Visual disturbance

Hearing impairment

Asthma

Temporary narrowing of the air passages leading to the lungs (Bronchospasm)

Shortness of breath (Dyspnea)

Excessive bloating (Distension)

Gastritis

Ulceration in the upper part of the small intestine (Duodenal ulcer)

Stomach ulcer (Gastric ulcer)

Oral ulceration

Gastrointestinal perforation

Hepatitis

Jaundice

Hepatic dysfunction

Itching

Hives (Urticaria)

Reddish-purple skin rash (Purpura)

Slightly pink swellings in the facial area (Angioedema)

Photosensitive reaction

Inflammation of the thin filtering units in the kidney (Tubulointerstitial nephritis)

Excessive protein excretion from the body via urine (Nephrotic syndrome)

Kidney failure (Renal failure)

Fatigue

## Rare

Viral meningitis (Aseptic meningitis) (especially in patients with autoimmune diseases such as Systemic Lupus Erythematosus (SLE) and mixed connective tissue disease)

Neck stiffness

Fever

Disorientation

Decrease in white blood cell count (Leukopenia)

Decrease in platelet count (Thrombocytopenia)

Sudden decrease in white blood cell count (Agranulocytosis)

Bone marrow's inability to produce blood (Aplastic anemia)

Premature breakdown of red blood cells (Hemolytic anemia)

Allergic reaction (Anaphylactic reaction)

Hallucinations, seeing or hearing things that are not real (especially in children)

Delusion (Paranoid delusion)

Excitability

Depression

Confusion (Confusional state)

Inflammation of the optic nerve (Optic neuritis)

Diseases of the optic nerve (Toxic optic neuropathy)

Tinnitus

Dizziness caused by problems in the body's balance system (Vertigo)

Heart failure

Accelerated heart rate (Tachycardia)

Palpitations

Chest pain (Angina pectoris)

Heart rhythm disorders (Cardiac dysrhythmias)

Increase in blood pressure

Liver damage

Irritant or non-irritant skin rashes

Cross-reaction with other sympathomimetic drugs

Eczema (Allergic dermatitis)

Swelling (Edema)

#### Very rare

Decrease in white, red blood cells and platelets (Pancytopenia)

Extensive destruction of red blood cells in a type of enzyme deficiency (Glucose-6-Phosphate Dehydrogenase (G6PD)) (Hemolysis)

Swelling of the face, tongue, and throat

Decrease in blood pressure (Hypotension)

Wheezing

Pancreatitis

Bullous skin inflammation, including Stevens-Johnson syndrome, characterized by blood pooling, swelling, and redness around the skin and eyes

A life-threatening skin disease characterized by blistering and peeling of the skin (Toxic epidermal necrolysis)

Rash in the form of blisters in the mouth and other areas of the body (Erythema multiforme)

Detection of blood in the urine (Hematuria)

Swelling occurring in parts of the body other than the heart and brain (Peripheral edema)

Increase in liver function test values

Decrease in oxygen-carrying capacity of blood (Decrease in hematocrit and hemoglobin)

### Unknown

Irritability

Anxiety disorder

Worsening of a type of inflammatory bowel disease (Exacerbation of Colitis and Crohn's disease)

A severe skin reaction known as DRESS syndrome (Drug Reaction with Eosinophilia and Systemic Symptoms) may occur. Symptoms of DRESS include: rash, fever, swollen lymph nodes, and increased eosinophils (a type of white blood cell).

Serious conditions affecting blood vessels in the brain, known as Posterior Reversible Encephalopathy Syndrome (PRES) and Reversible Cerebral Vasoconstriction Syndrome (RCVS)

If symptoms that may indicate Posterior Reversible Encephalopathy Syndrome (PRES) and Reversible Cerebral Vasoconstriction Syndrome (RCVS) develop, stop using IBUCOLD C immediately and seek urgent medical attention:

Sudden severe headache

Feeling unwell

Vomiting

Confusion

Seizures, changes in vision

### Reporting of side effects

#### Reporting of side effects

If you experience any side effects not listed in this leaflet, talk to your doctor, pharmacist, or nurse. You can also report side effects you encounter to the Turkish Pharmacovigilance Centre (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on [www.titck.gov.tr](http://www.titck.gov.tr) or by calling the side effect notification line 0 800 314 00 08. By reporting side effects, you will contribute to obtaining more information about the safety of the medicine you are using.

*If you experience any side effects not mentioned in this patient information leaflet, inform your doctor or pharmacist.*

### How to store IBUCOLD C

*Keep IBUCOLD C out of the sight and reach of children and in its packaging.*

Store in a dry place at room temperature below 25 °C.

**Use in accordance with the expiry date.**

*Do not use IBUCOLD C after the expiry date on the packaging.*

**To protect the environment**

“Do not throw expired or unused medicines into the trash! Give them to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.”

**License holder:**

Humanis Sağlık A.Ş Maslak/Sarıyer/İstanbul

**Manufacturer:**

Humanis Sağlık A.Ş Kapaklı/Tekirdağ

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