

PATIENT INFORMATION LEAFLET

İBURAMİN COLD 200 mg/30 mg/2 mg film coated tablets

Taken orally.

- **Active substance:** Each film coated tablet contains 222.22 mg ibuprofen DC 90% equivalent to 200 mg ibuprofen, 30 mg pseudoephedrine HCl, and 2 mg chlorpheniramine maleate.
- **Excipients:** Lactose monohydrate (derived from cow milk), microcrystalline cellulose PH 102, povidone K30, magnesium stearate, colloidal silicon dioxide, croscarmellose sodium, hypromellose, polyethylene glycol, titanium dioxide (E171) and carmoisine (azorubin) aluminium lac (E122).

Read this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because 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 only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. *What İBURAMİN COLD is and what it is used for?*
2. *What you need to know before you take İBURAMİN COLD?*
3. *How to take İBURAMİN COLD?*
4. *Possible side effects*
5. *How to store İBURAMİN COLD?*

1 .What İBURAMİN COLD is and what it is used for?

- İBURAMİN COLD is marketed in PVC/PVDC/Al blisters as 12 and 24 film-coated tablets. Each film coated tablet contains 200 mg ibuprofen, 30 mg pseudoephedrine hydrochloride and 2 mg chlorpheniramine maleate.
- Chlorpheniramine is an antihistaminic agent decreasing natural histamine of the body. Histamine causes sneezing, itching, watering of eyes, and running nose. Ibuprofen belongs to non-steroid anti-inflammatory drugs group. Ibuprofen decreases hormones, which lead to pains and inflammation in the body. Pseudoephedrine is a decongesting substance, which constricts blood vessels in the nasal passages. Dilated blood vessels cause nasal blockage.

IBURAMIN COLD; is used for the relief of symptoms associated with common cold, flu, sinusitis and other upper respiratory tract infections such as fever, runny nose and nasal congestion.

2 .What you need to know before you take IBURAMIN COLD

DO NOT take IBURAMIN COLD under these conditions

Risks related to Cardiovascular System

- Non-steroidal anti-inflammatory drugs (NSAIDs) may cause a potentially fatal coagulation (KV thrombotic) event, a heart attack (myocardial infarction) and an increased risk of stroke. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

-IBURAMIN COLD should not be used (contraindicated) for treatment of pain before surgery performed to improve obstruction in coronary veins (coronary artery by-pass surgery).

Risks Related to Digestive System

Non-steroidal anti-inflammatory drugs (NSAIDs) cause serious adverse events associated with the gastrointestinal system including bleeding, ulceration and perforation of the stomach or intestines, which can be fatal. These adverse events can occur at any time with or without prior warning symptoms. Elderly patients are at a greater risk for serious gastrointestinal events.

Do not take IBURAMIN COLD,

- If you have hypersensitivity to ibuprofen, pseudoephedrine, chlorpheniramine, any of the excipients in the product, or other adrenergic drugs
- If you have a disease accompanied by a severe hypertension and tachycardia
- If you are in the last trimester of pregnancy
- If you have severe liver disease
- If you have severe kidney failure
- For children younger than 12 years old
- If you have coronary artery (blood vessel for the heart) disease
- If you are using these drugs: some of the antidepressants, atropine used for the treatment of eye and intestinal disorders, antihypertensive drugs containing alpha and beta blockers, drugs used for blood aggregation and asthma treatment, appetite suppressing agents, moclobemide used for mood disorders, ergotamine or methysergide used for migraine treatment, oxytocin used during delivery to help uterine contractions
- If you are using drugs called as monoamine oxidase (used in the treatment of depression) inhibitors or if not more than 2 weeks have passed over the treatment you had with those drugs
- If you have previously showed allergic reactions such as asthma, nasal inflammation (rhinitis), or hives (urticaria) against ibuprofen, aspirin, and other non-steroidal anti-inflammatory drugs (NSAIDs)
- If you have had a previous gastrointestinal bleeding or perforation because of the mentioned drugs

- If you have had diseases such as recurrent gastrointestinal ulcers, inflammatory bowel diseases (ulcerative colitis, Crohn's disease), gastrointestinal bleeding or you have had them before repetitively
- If you have severe cardiac failure (NYHA Class IV)
- If gastrointestinal bleeding or wounds (ulcerations) occur during ibuprofen use
- If you have a condition which increases your tendency to bleeding
- If you are taking another sympathomimetic drug (decongestant, appetite suppressor drugs or amphetamine like drugs) or blood pressure reduction beta blocker drug
- During the period before or after coronary artery by-pass surgery (a surgery to improve obstruction in coronary veins)

Use İBURAMİN COLD with CAUTION

- If you have high blood pressure and heart disease
- If you have diabetes mellitus
- If you have overworking thyroid gland
- If you have high eye tension (glaucoma)
- If the patient has pheochromocytoma (it is a tumor in the adrenal glands, and it may cause increased adrenaline)
- If you have a rhythm disorder in your heart
- If you have enlarged prostate and disordered urinary bladder
- If you are previously diagnosed or suspected to have elongated QT syndrome (severe rhythm disorder in the heart and it may cause sudden death) and Torsade de Pointes (irregular heart rhythm endangering life)
- If you are taking oral corticosteroids, drugs that prevent blood clotting (anticoagulants) (example: warfarin)
- Seldom posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) have been reported with sympathomimetic drugs including pseudoephedrine. Reported symptoms were sudden onset severe headache, nausea, vomiting, and visual disturbances. Majority of cases were recovered in a few days by the appropriate treatment. Pseudoephedrine should immediately be stopped when PRES/RCVS sign and symptoms are developed
- If you are older than 60 years old
- It may cause narrowing of the respiratory tract (bronchial spasm) if you are an asthma patient or you had a previous asthma attack
- If you previously had gastrointestinal ulcers or other gastrointestinal diseases , they may flare up
- If you have kidney disease, the kidney functions should be followed up. The risk of kidney function worsening is increased in people, who take ibuprofen and similar NSAIDs for a long time; who have heart failure and liver disorders; who take drugs increasing urine output (diuretics) and antihypertensive drugs belonging to ADE inhibitor class; and who are elderly
- If you have liver disease
- If you have heart disease or hypertension (high blood pressure); fluid retention and as a result of it swellings (edema) may be observed in various parts of the body
- When ibuprofen and similar drugs are used for especially at high doses (2400 mg/day), they were detected to be related to a small increase in risk of heart attack (myocardial infarction) or stroke. Treatment should be consulted with the physician or the pharmacist in people who have heart or vascular diseases; have previous stroke or have risks for such conditions (high blood pressure, high cholesterol or diabetes disease or smokers)

- If ibuprofen and similar non-steroidal anti-inflammatory drugs (NSAIDs) are used for a long time period (continuous use), although you have not had such a disease before, ulcers, bleeding and perforations may occur in the gastrointestinal tract. The risk of such undesired effects is increased in subjects who have had such a disease before, in elderly people, at high drug doses, and during long-term treatments
- If you realize purple coloring or bruises without unknown origin in your body, consult your physician
- Immediately consult your physician if there are tremor and sudden increase in fever, malaise, headache and vomiting or neck stiffness; these may be symptoms of a type of brain membrane inflammation (aseptic meningitis)
- If hallucinations, irritability, and sleep disturbances occur, then stop taking the drug.
- If you have seizures (epilepsy) disease
- If you have redness and rash on your skin, then you should immediately consult your physician
- Do not use it more than 5 days

Similar to the other non-steroidal anti-inflammatory drugs (NSAIDs), İBURAMİN COLD can also mask signs of infection.

The administration of the lowest dose which will relieve the signs of your disease for the shortest treatment duration will minimize the undesired effects of the drug.

If these warnings are valid for you even for any period in the past, please consult your doctor.

İBURAMİN COLD with food and drink

Do not take İBURAMİN COLD with alcohol. If you drink more than three glasses of alcohol in a day, ibuprofen may increase gastric bleeding risk. Do not take it with orange juice and cola. Take İBURAMİN COLD Film Coated Tablets either at least one hour before or two hours after these foods.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Use of İBURAMİN COLD may be harmful for the baby during the pregnancy, especially in the last three months of pregnancy. Do not take this drug unless it is recommended by your physician.

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

Breastfeeding

Consult your doctor or pharmacist before taking this medicine.

İBURAMİN COLD can excrete into breast-milk, and this may be harmful for the baby. If you are breast feeding your baby, do not take this drug without consulting your physician.

Effects on ability to drive and use of machines

İBURAMİN COLD Film Coated Tablets may have side effects which may give harm to your thoughts or reactions. If you are driving, or you are doing anything that you should be awake you should be careful.

Important information about some excipients contained in İBURAMİN COLD

As it contains lactose monohydrate, if you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking İBURAMİN COLD Film Coated Tablets.

It may cause allergic reactions due to the colorants carmoisine (azorubin) aluminium lac (E122) in its composition.

Usage with other medicines

Because interactions were reported in some patients, when you are having İBURAMİN COLD treatment you should be careful if you are receiving any of the drugs listed below:

- Aminoglycoside class antibiotics (i.e. gentamicin, kanamycin, streptomycin);
- Drugs for high blood pressure,
- ADE inhibitors, beta-blockers and diuretics used in the treatment of hypertension
- Cholestyramine used in the treatment of high cholesterol
- Sulfonylurea drugs used to lower the blood sugar level
- CYP2C9 inhibitors (drug group which stops proteins responsible for neutralization of drugs in the liver) (i.e. voriconazole, fluconazole)
- Drugs preventing blood coagulation (i.e. warfarin)
- Drugs inhibiting thrombocytes, which provide coagulation (antithrombocyte agents, i.e. aspirin, dipyridamole, clopidogrel) and selective serotonin re-uptake inhibitors used for depression (i.e., fluoxetine, fluvoxamine, paroxetine, sertraline)
- Aspirin
- Ginkgo biloba herbal extract
- Drugs increasing urine output (i.e. furosemide)
- Cardiac glycosides used for heart failure (i.e. digoxin, digitoxin)
- Caution should be exercised when using it in conjunction with captopril, a kind of blood pressure medication
- Quinolone class antibiotics (i.e. ciprofloxacin); seizures (convulsion)
- Other analgesics (other NSAIDs including COX-2 inhibitors; i.e. aspirin, naproxen, celecoxib, nimesulide)
- Cortisone group drugs
- Lithium salts (used in psychiatric disease treatments) and methotrexat (a drug used in rheumatic joint diseases, and in some cancer types)
- Mifepristone (miscarriage drug)
- An antibiotic, Cyclosporine
- Tacrolimus, a drug used to prevent your body from rejecting the transplanted organ after organ transplant operations
- Zidovudine used in the treatment of AIDS (HIV infection)
- Classical antihistamines used in the treatment of allergic diseases (with sedative [calming, quietening] effect)
- Phenytoin containing epilepsy drugs, in dismay, fear (anxiety) treatment or sleep regulating drugs

- Monoamine oxidase inhibitor (MAOI) group drugs used in the treatment of nasal obstruction, tricyclic antidepressants used in the treatment of psychiatric disorders, appetite suppressants and certain nervous system stimulating drugs or psychiatric disorders, bretylium, betanidine, guanitidine, dextrin, methyldopa and alpha drugs such as beta-adrenergic blockers
- Moclobemide used in depression treatment
- Cardiac glycosides (used in heart failure)
- Ergot alkaloids (ergotamine and metisergide; used in migraine treatment)
- With ergot alkaloids used in the treatment of migraine (eg, ergotamine and methysergide)
- Oxytocine which is used to help delivery
- Tricyclic antidepressants used in depression treatment

If you are currently using or recently used a prescribed or non-prescribed medicine, please inform your doctor or pharmacist about it.

3. How to take İBURAMİN COLD?

- **Instructions for appropriate usage and dose/application frequency:**

This drug must be used exactly as described in the patient information leaflet or as recommended by your doctor. Do not use this drug in larger quantities or longer than recommended. This drug is usually used for a short time until your signs of disease disappear. Overdose of ibuprofen may harm your stomach and intestines.

İBURAMİN COLD is used as 1 or 2 film-coated tablets every 4 or 6 hours, maximum 6 film coated tablets within 24 hours for at most 5 days. Use the smallest dose İBURAMİN COLD that will treat your pain, fever and cold.

You should definitely inform your doctor if your fever persists longer than three days or if your complaints have not resolved although you have used the drug for 5 days or if new signs of disease have emerged. In case you will undergo any surgical operation or if you have used this drug a few days ago, inform your doctor at the start of the operation. Allergy skin tests may give unanticipated results while you are using this drug.

Keep this drug at room temperature away from moisture and heat.

- **Route and method of administration:**

İBURAMİN COLD is only for oral use.

- **Different age groups:**

Pediatric Use:

Do not use it for children under 12 years of age.

Geriatric use:

İBURAMİN COLD may increase the risk of gastric bleeding in patients older than 60 years of age.

- **Special Usage Conditions:**

Kidney/Liver failure:

Do not use İBURAMİN COLD in cases of severe kidney and liver failures.

If you feel that the effect of İBURAMİN COLD is too weak or too strong, talk to your doctor or pharmacist.

If you have taken İBURAMİN COLD more than you should:

If you have taken İBURAMİN COLD more than you should, consult your doctor or pharmacist.

If you forget to take İBURAMİN COLD:

Do not take a double dose to make up for the missed dose of İBURAMİN COLD.

Omit the missed dose, and take the next dose at the planned dose time.

Effects that may occur when treatment with İBURAMİN COLD is discontinued:

None.

4. Possible side effects

As it is for all medicines, side effects can be seen in people who are sensitive to the ingredients of İBURAMİN COLD.

Side effects were listed as shown in the following categories:

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

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

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients .

Unknown: it cannot be estimated from the available data.

If you experience any of the following, stop using İBURAMİN COLD and IMMEDIATELY consult your doctor or apply to the emergency service of the nearest hospital:

- Shortness of breath; swelling of your face, lips, tongue, eye lids or throat; severe itching and rash on the skin; palpitations and dizziness resulting from low blood pressure (hypersensitivity – allergy)
- Wheezing or difficult breathing (asthma attack)
- Increased blood pressure (hypertension)
- Irregular heart rate, palpitations, chest pain
- Severe stomach pain (stomach ulcers or pancreatitis)
- Yellowing of the eyes and skin (liver dysfunction)
- Any blood or black color that look like coffee grounds in stool or vomit (gastrointestinal bleeding)
- Skin bruising, bleeding of the nose and gums, increased incidence of infectious diseases, pale skin and fatigue (bone marrow suppression)
- A disease on the skin, eyes and around genitals associated with peeling, swelling and blistering of the skin and fever (erythema multiforme)
- A serious disease associated with skin blisters filled with liquid and peeling and loss of the skin (toxic epidermal necrolysis)
- Sudden loss of muscle strength, loss of sensation, visual disorders (stroke)
- Severe headache, stiffness of the neck, nausea, vomiting and decreased level of consciousness (aseptic meningitis)
- Seeing or hearing things that are not real (hallucinations)

All of these side effects are very serious.

If you have one of the followings, then it means that you have a severe allergy against IBURAMIN COLD. You may need emergency medical care or hospitalization.

Such serious side effects are very rare.

IMMEDIATELY contact your doctor or apply to the emergency service of the nearest hospital, if you experience any of the following symptoms:

Common:

- Nervousness, sleeplessness
- Light-headedness, headache, and dizziness
- Blurred vision
- Digestive problems (dyspepsia)
- Frequent defecation (diarrhea)
- Nausea, vomiting, abdominal pain
- Excessive floating in stomach and intestines (flatulence)
- Decreased or diminished colon motility (constipation)
- Gastrointestinal bleeding
- Tar colored, foul smelling defecation (melaena)
- Bloody or coffee grain vomitus (hematemesis)
- Rash

Uncommon:

- Visual defects
- Wound in duodenum (duodenal ulcer)
- Wound in the stomach (gastric ulcer)
- Inflammation of the inner membrane of the stomach (gastritis)
- Mouth inflammation prominent by small wounds (oral ulceration)
- Jaundice
- Liver inflammation (hepatitis)
- Liver function disorder
- Hurry, irritability
- Numbness (paresthesia)
- Hearing disorder (decreased or increased hearing)
- Common cold (rhinitis), influenza
- Fatigue
- Asthma, deterioration of asthma, bronchospasm or difficulty in breathing (dyspnea) like respiratory tract reactions
- Hives (urticaria)
- Itching (pruritus)
- Small hemorrhages on the skin and mucosa (purpura)
- Hypersensitivity (angioedema) causing swelling in the face and throat (edema)
- Sensitivity to light (photosensitivity)
- Painful urination
- Difficult urination in male patients (urinary retention)
- Kidney failure (swelling of ankles)

Rare:

- Decreased number of white blood cells (leukocyte) (leukopenia)
- Decreased number of cells mediating thrombocyte-blood coagulation (thrombocytopenia)
- Sudden onset, decreased number of white blood cells (agranulocytosis)
- Severe depletion of blood cells (aplastic anemia)
- Hemolytic anemia (a type of anemia)
- Excessive decrease of neutrophil number in the blood (neutropenia)
- Ringing in the ears (tinnitus)
- Seeing, feeling or hearing fictitious things (hallucination)
- Dizziness due to a pathology in the inner ear (vertigo)
- Inflammation of the linings of brain (stiffness of the neck, headache, nausea, vomiting, fever, sensitivity to the light or loss of orientation (perception of place, time, environment)) (aseptic meningitis)
- Widespread, severe allergic reaction (anaphylaxis)
- Delirium
- Increased heart rate (tachycardia)
- High blood pressure (hypertension)
- Disorder in the heart rhythm
- Inflammation in the eye nerve (optic neuritis)
- Being sleepy (somnia)
- Inflammation in the eye due to a toxic substance (toxic optic neuropathy)
- Dry mouth
- Perforation in the stomach or intestines (gastrointestinal perforation)
- Damage in the liver
- Edema
- Skin rash as a result of allergy (allergic dermatitis)

Very rare:

- Pancreas inflammation (pancreatitis)
- Liver failure
- In the skin, mouth, eyes, genital organs; severe bullous skin inflammation, including Stevens-Johnson syndrome with skin peeling, swelling, bubbles and fever
- A disease with red skin rashes of different sizes or with collection of water in mouth and other areas of the body (erythema multiforme)
- A severe disease which is encountered by water filled swellings on the skin, skin peeling, and tissue loss (toxic epidermal necrolysis)
- Obstruction of heart arteries by a blood clot

Unknown:

- Allergic reaction and angioedema
- Increased excitability and anxiety (concern, worry)
- Loss of appetite
- Gastrointestinal inflammation (colitis) and inflammation of Crohn's disease, a kind of inflammatory bowel disease
- Blood disorders (dyscrasias)
- Thickening of sputum

Drugs like İBURAMİN COLD, especially at high doses (2400 mg/day), may cause a small increase in the risk of heart attack (myocardial infarction) or stroke.

Rarely İBURAMİN COLD may cause blood disorders and kidney problems.

All of these are severe side effects. Emergent medical care may be required.

If any of the following happens, tell your doctor:

- Diarrhea, constipation, abdominal ache, indigestion, dry mouth, rash, irritability or anxiety, fatigue, headache, jaundice, edema, bleeding that lasts longer than normal

If you experience any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5 . How to store İBURAMİN COLD

Keep İBURAMİN COLD out of the sight and reach of children and in its package.

Keep at room temperature below 25°C.

Use in accordance with its expiry date.

Use İBURAMİN COLD before the expiry date indicated on the blister or the package.

Do not use İBURAMİN COLD if you notice any defect in the product and/or its packaging.

Marketing authorization holder:

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/ İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

This patient information leaflet was last approved on 07/06/2018.