

PATIENT INFORMATION LEAFLET

IBURAMIN COLD 100 mg/15 mg/ 1mg/5 ml syrup

Use orally.

- **Active substance:** Each 5 ml (1 measuring spoon) syrup contains 100 mg ibuprofen, 15 mg pseudoephedrine hydrochloride and 1 mg chlorpheniramine maleate.
- **Excipients:** Methylparaben sodium (E219), sodium bicarbonate, sodium cyclamate, sodium carboxymethyl cellulose, sorbitol (70%) (E420), sodium hydroxide, polyoxyl 40 castor oil, sucrose, banana essence, sunset yellow (E110), purified water.

Read this PATIENT INFORMATION LEAFLET carefully before you start using 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 IBURAMIN COLD is and what it is used for?***
2. ***Before you use IBURAMIN COLD***
3. ***How to use IBURAMIN COLD?***
4. ***Possible side effects***
5. ***How to store IBURAMIN COLD?***

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

- IBURAMIN COLD is a syrup that yellow colored, clear solution with aromatic odor (banana), available in 100 ml amber glass bottle with a measuring spoon graduated at 2.5 and 5 ml. Each 5 ml of syrup contains 100 mg ibuprofen, 15 mg pseudoephedrine hydrochloride and 1 mg chlorpheniramine maleate.
- Chlorpheniramine is an antihistaminic drug 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. Before you use IBURAMIN COLD

DO NOT use IBURAMIN COLD in the following 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.

If;

- You have hypersensitivity to ibuprofen, pseudoephedrine, chlorpheniramine, any of the excipients in the product, or other adrenergic drugs
- You are in the last trimester of pregnancy
- You have severe liver disease
- You have severe kidney failure
- For children younger than 6 years old
- You have blood vessel for the heart (coronary artery) disease
- 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
- You are using drugs which is using in depression treatment called as monoamine oxidase inhibitors or if not more than 2 weeks have passed over the treatment you had with those drugs
- You have previously showed allergic reactions such as asthma, nasal inflammation (rhinitis), or hives (urticaria) against ibuprofen, aspirin, and other NSAIDs
- You have had a previous gastrointestinal bleeding or perforation because of the mentioned drugs
- 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
- Gastrointestinal bleeding or wounds (ulcerations) occur during ibuprofen use

- You have a condition which increases your tendency to bleeding
- You are taking another sympathomimetic drug (decongestant, appetite suppressor drugs or amphetamine like drugs) or beta blocker drug
- During the period before or after coronary artery by-pass surgery (a surgery to improve obstruction in coronary veins)
- You have severe cardiac failure (NYHA Class IV)
- You have high blood pressure and heart disease
- You have diabetes mellitus
- You have overworking thyroid gland
- You have high eye tension (glaucoma)
- The patient has pheochromocytoma (it is a tumor in the adrenal glands, and it may cause increased adrenaline)
- You have a rhythm disorder in your heart
- You have enlarged prostate and disordered urinary bladder

Take special care with IBURAMIN COLD in the following conditions

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 Torsades de Pointes (irregular heart rhythm endangering life)
- You are taking oral corticosteroids, anticoagulants (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
- You are older than 60 years old
- It may cause bronchial spasm if you are an asthma patient or you had a previous asthma attack
- You previously had gastrointestinal ulcers or other gastrointestinal diseases, they may flare up
- 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 ACE inhibitor class; and who are elderly
- You have liver disease
- 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 and for long-time periods, 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)
- Ibuprofen and similar 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

- 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)
- Hallucinations, irritability, and sleep disturbances occur, then stop taking the drug
- You have epilepsy (seizures) disease
- 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 NSAIDs, IBURAMIN 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.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using IBURAMIN COLD with food and drink:

Do not take IBURAMIN 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 IBURAMIN COLD either at least one hour before or two hours after these foods.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

Use of IBURAMIN 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 notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking the medicine.

IBURAMIN 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

IBURAMIN COLD may have side effects which may harm 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 of the excipients of IBURAMIN COLD

Since it contains sucrose and sorbitol (E420), if you have been told by your doctor that you have weakness (intolerance) to some sugars, consult your doctor before taking this medicinal product.

This medicinal product contains approximately 38 mg of sodium per 5 ml dose. This should be taken into consideration for patients on a controlled sodium diet.

IBURAMIN COLD contains sunset yellow (E110), therefore it may cause allergic reactions. These allergic reactions are more common in people who are allergic to aspirin.

As it contains methylparaben sodium (E219), it may cause delayed allergic reactions.

As it contains polyoxyl 40 castor oil, it may cause nausea and diarrhea.

Using with other medicines

Because interactions were reported in some patients, when you are having IBURAMIN 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 blood sugar level
- Mifepristone (miscarriage drug)
- CYP2C9 inhibitors (such as voriconazole, fluconazole), a group of drugs that stop the proteins that are involved in neutralizing drugs in the liver
- 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)
- Some kind of blood pressure medication, Captopril
- 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)
- An antibiotic, cyclosporine
- Tacrolimus, a drug used to prevent your body from rejecting the transplanted organ after organ transplant operations
- Blood-diluting drugs called ticlopidine
- Zidovudine used in the treatment of AIDS (HIV infection)
- Classical antihistaminics (with sedative [calming, quietening] effect)
- Phenytoin containing epilepsy drugs, in anxiety (dismay, fear) 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, methyl dopa and alpha drugs such as beta-adrenergic blockers
 - Moclobemide used in the treatment of depression
 - Cardiac glycosides (used in heart failure)
 - Ergot alkaloids (i.e., ergotamine and metisergide; used in migraine treatment)
 - Oxytocine which is used to help delivery
 - Tricyclic antidepressants (used in depression treatment)

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use IBURAMIN COLD?

• Instructions for appropriate method and dose/frequency of administration:

Fever therapy: Fever reducer (antipyretic) action lasts approximately 6 to 8 hours and is not prolonged with the use of higher doses. Doses should be adjusted according to the table provided below.

It should not be used more than 5 days.

AGE	5 mg/kg Fever \leq 39.2°C		10 mg/kg Fever $>$ 39.2°C	
	mg	Spoon	mg	Spoon
6-8 years of age	125	1+ 1/4	250	2+ 1/2
9-10 years of age	150	1+1/2	300	3
11-12 years of age	200	2	400	4

In adolescents above 12 years of age and adults, 1 to 2 spoonful is taken 3 to 4 times a day.

It is not used for children under 6 years of age.

To minimize the undesired effects, the lowest effective dose for management of the symptoms should be used for the shortest possible duration.

• Route and method of administration:

IBURAMIN COLD is only for oral use.

It is taken by using the graduated spoon.

• Different age groups

Use in children:

It is not used for children under 6 years of age.

Use in elderly:

The risk of ibuprofen-induced gastric hemorrhage increases in individuals over 60 years of age.

• Special populations:**Kidney/Liver failure:**

It should not be used in patients with impaired liver and kidney function.

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

If you have used more IBURAMIN COLD than you should:

If you may have taken more IBURAMIN COLD than you should, or if children have used this medicine by accident, always consult a doctor or nearest hospital for advice and advice on risk to be taken.

Symptoms; nausea, abdominal pain, vomiting (bloody lines), headache, ringing in the ears, blurring of consciousness, and wobbly eye movements. In high doses, drowsiness, chest pain, palpitation, loss of consciousness, contractions (especially in children), weakness and dizziness, blood in the urine, chills, respiratory problems have been reported.

Acute overdose may cause central nervous system stimulation, and clinical signs of variable cardiovascular effects. Blood pressure boosting drugs (pressor amines) should be very careful used in the presence of pseudoephedrine HCl. Patients with overdose signs should be conservatively treated.

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

If you forget to use IBURAMIN COLD:

Take the next dose at the planned dose time.

Do not use double dose to make up for the dose you forgot.

If you stop using IBURAMIN COLD:

None.

4. Possible side effects

Like all medicines, side effects can occur in people sensitive to the contents of IBURAMIN COLD.

If any of the following occur stop using IBURAMIN COLD and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- 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/or 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)
- A severe skin reaction known as DRESS syndrome may occur. The indications of DRESS are; rash, fever, swelling of lymph nodes, and eosinophils (a kind of white blood cell) increase.

These are all very serious side effects.

If you get any of these, this indicates you have serious hypersensitivity to IBURAMIN COLD. You may need emergency medical care or hospitalization.

Such serious side effects are very rare.

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 notice any of the following immediately inform your doctor or go to the nearest emergency department:

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 (somnolence)
- 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
- Serious bullous skin inflammation including Stevens-Johnson syndrome (a condition occurring on the skin, mouth, eyes, and around genitals and associated with peeling, swelling, blistering of the skin 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 hypersensitivity reaction (angioedema) causing swelling in the face and throat (edema)
- Increased excitability and concern, worry (anxiety)
- Loss of appetite
- Inflammation of colon (colitis) and exacerbation of Crohn's disease, a kind of inflammatory bowel disease
- Hemolytic anemia (a type of anemia)
- Blood disorders (dyscrasias)
- Thickening of sputum

Drugs like IBURAMIN COLD may cause a small increase in the risk of heart attack (myocardial infarction) or stroke.

Rarely IBURAMIN COLD may cause blood disorders and kidney problems. All of these are severe side effects. Emergent medical care may be required.

Serious side effects occur very rarely.

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

5. How to store IBURAMIN COLD

Keep in the original package and out of the reach and sight of children.
Store below 25 °C at room temperature.

Use in accordance with the expiry date.

Use IBURAMIN COLD before the expiry date indicated on the label or carton.

Do not use IBURAMIN COLD if you notice any damage to the product and/or package.

Marketing authorization holder:

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