

## PATIENT INFORMATION LEAFLET

### **DROFLU COLD 200 mg/30 mg tablet**

**It is taken orally.**

- **Active ingredient:** Each tablet contains 200 mg of ibuprofen and 30 mg of pseudoephedrine hydrochloride.
- **Excipients:** Calcium hydrogen phosphate anhydrate, microcrystalline cellulose, croscarmellose sodium, povidone K-30, colloidal anhydrous silica, magnesium stearate

**Before you start using this medicine, carefully read this INSTRUCTIONS FOR USE, because it contains important information for you.**

- *Keep this user manual. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *When you go to the doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.*
- *Follow exactly what is written in this instruction. Do not use high or low doses other than the dose recommended to you about the drug.*

#### **In this leaflet:**

- 1. What is DROFLU COLD and what is it used for?***
- 2. Things to consider before using DROFLU COLD***
- 3. How to use DROFLU COLD?***
- 4. What are the possible side effects?***
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**Headings are included.**

**1. What is DROFLU COLD and what is it used for?**

DROFLU COLD is a medicine presented in blister packs of 20 and 24 tablets. DROFLU COLD contains ibuprofen and pseudoephedrine as active ingredients.

Ibuprofen, the active ingredient of DROFLU COLD, is a nonsteroidal anti-inflammatory drug with analgesic and antipyretic properties. Pseudoephedrine is a decongestant drug that helps to relieve the fullness of the nose and sinuses (nasal cavities).

Thanks to its analgesic, antipyretic and anti-inflammatory effects, DROFLU COLD is mainly used for the treatment of the following conditions:

- Nasal congestion, headache, fever, body aches and other pains observed in the course of flu, colds and sinusitis

**2. Things to consider before using DROFLU COLD**  
**DO NOT USE DROFLU COLD in the following situations**

**Risks related to the cardiovascular system**

- NSAIDs can increase the risk of potentially fatal thrombotic (clotting-related) events, heart attack, and stroke (stroke). This risk may increase with the duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at higher risk.

- DROFLU COLD should not be used in the treatment of pain before coronary artery “bypass” surgery.

**Risks related to the digestive system**

- NSAIDs cause serious undesirable effects such as bleeding, sores, perforation of the stomach or intestines, which can be fatal. These undesirable effects can occur at any time, with or without a pre-warning symptom. Elderly patients are at higher risk for these serious effects.

If,

- If you are hypersensitive to any of the ingredients of DROFLU COLD,
- if you have severe liver disease,
- if you have severe kidney failure,
- If you have experienced asthma, urticaria or allergic type reaction while using acetylsalicylic acid (Aspirin) and 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 pregnant,
- If you are going to have or have just had coronary artery bypass surgery,
- If you have high blood pressure and coronary artery insufficiency (narrowing of the vessel feeding the heart),
- If you have a bleeding or other active bleeding related to cerebral vessels,
- If you are using a monoamine oxidase inhibitor for the treatment of your depression or mood disorder, or if you have used it in the last 14 days,
- if you have severe heart failure (NYHA Class IV),
- Medicines used in the treatment of depression, atropine used in the treatment of eye or intestinal disorders, blood pressure medicines containing alpha or beta blockers, medicines related to blood coagulation, medicines used in the treatment of asthma, appetite suppressants, moclobemide used in mood disorders, ergotamine or methysergite used in the treatment of migraine, if you are using any of the drugs used during childbirth, such as oxytocin, which cause uterine contraction,
- Children under 12 years old,
- If you are breastfeeding
- If your thyroid gland works fast, if you have an increase in eye pressure, if you have diabetes,
- If you have pheochromocytoma disease (it is a tumor that occurs in the adrenal glands and can cause an increase in the amount of adrenaline).

**USE DROFLU COLD CAREFULLY in the following situations**

Your doctor will decide whether to use DROFLU COLD for you or your child in the following cases.

If;

- Avoid using it together with any of the drugs that are effective against pain, fever and inflammation.
- If stomach pain occurs, stop using the drug and consult your doctor.
- If you have a previous serious gastrointestinal disorder or symptoms, bleeding, ulcers or damage, which can be serious, may develop at any time during treatment. Depending on the bleeding that may occur, darkening of the stool color, blood coming from the mouth, indigestion symptoms may occur. For this

reason, if you have serious gastrointestinal disorders such as ulcer bleeding and destruction, your doctor will recommend that you start the treatment with the lowest dose and use some protective drugs (misoprostol or proton pump inhibitors) together.

- Do not continue to use DROFLU COLD in cases of exfoliation of the skin, mucous membrane damage or hypersensitivity observed on the skin, consult your doctor as soon as possible.
- Use with caution in cases of hypersensitivity such as swelling of the face and throat as a result of allergies, difficulty in breathing, narrowing of the bronchi (asthma) and colds.
- Consult your doctor if bruises and bruises occur on your body for no reason.
- If you experience chills, chills and sudden increase in fever, weakness, headache and vomiting or a feeling of stiffness in your neck, consult your doctor immediately; because there may be signs of a type of meningitis (aseptic meningitis).
- As with other pain, fever and inflammation drugs, DROFLU COLD should be used with caution in patients with kidney disease. Diğer ağrı, ateş ve iltihaba etkili ilaçlar ile olduğu gibi, DROFLU COLD, karaciğer fonksiyon testinde bazı değerlerinizde yükselmelere neden olabilir. Karaciğer fonksiyonlarındaki bozulmayı gösteren belirti ve bulgulara karşı dikkatli olunmalıdır (bulantı, halsizlik, uyuklama, kaşıntı, sarılık, karnın sağ üst kısmında ağrı, nezle benzeri semptomlar).
- Since ibuprofen prolongs the bleeding time by reducing the aggregation of platelets involved in coagulation in your blood, if you have a coagulation disorder, continue DROFLU COLD treatment under the control of a doctor.
- If you develop visual impairment while using DROFLU COLD, have an eye examination.
- If you have a high blood pressure problem or heart failure, be careful when using DROFLU COLD against 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 (eg high blood pressure, diabetes) or have high cholesterol, do not exceed the specified daily dose if you smoke.

- As with other pain, fever and inflammatory drugs, DROFLU COLD can cause serious side effects such as heart attack or stroke, which can result in hospitalization or death. Although serious cardiovascular system events can occur without any warning signs, consult your doctor when signs and symptoms such as chest pain, shortness of breath, weakness, and difficulty in speaking are observed.
- Consult your doctor if you have unexplained weight gain or signs of edema (ankle swelling).
- Do not use for longer than 5 days.
- If you are over 60, use it carefully.
- If you have prostate enlargement and urinary bladder dysfunction, you should use the drug carefully.
- If you have Systemic Lupus Erythematosus (SLE), a connective tissue disease, consult your doctor before use.
- Since the risk of serious side effects such as bleeding and perforation in the gastrointestinal tract, which can be fatal, especially in the elderly, is higher, it should be used with caution.
- If you are an athlete, the doping test may be positive.
- Sudden onset, severe abdominal pain, nausea, vomiting and visual disturbances may develop with drugs that stimulate the sympathetic system, including pseudoephedrine. If these symptoms occur, pseudoephedrine treatment should be discontinued immediately.
- If you have been diagnosed with prolonged QT syndrome (a condition that can lead to severe heart rhythm disturbance and sudden death) and Torsades de Pointes (life-threatening irregular heart rhythm), or if you are suspected of having these diseases, you should use the drug carefully.

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

### **Using DROFLU COLD with food and drink**

Interaction with food and drink has not been reported.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

DROFLU COLD should not be used during pregnancy.

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

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

Pseudoephedrine is excreted in significant amounts, although ibuprofen is known to pass into breast milk in very low amounts.

DROFLU COLD should not be used during breastfeeding.

### **Vehicle and machine use**

Do not drive or use machines as dizziness may develop while using DROFLU COLD.

### **Important information about some of the ingredients of DROFLU COLD**

This product contains 1 mmol (23 mg) sodium in each dose. This should be considered for patients on a controlled sodium diet.

### **Concomitant use with other drugs**

- High blood pressure medications; may reduce its blood pressure lowering effects.
- Anticoagulants (drugs that prevent or delay blood clotting) such as warfarin or heparin may increase their anticoagulant effects.
- 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.
- Ginkgo biloba herbal extract may increase the risk of bleeding in the gastrointestinal tract.
- When used together with cortisone group drugs, the risk of ulcers and bleeding in the gastrointestinal tract may increase.
- Urinary excretion of aminoglycoside antibiotics (eg gentamicin, kanamycin, streptomycin) may be decreased and their undesirable effects may increase.
- The effect of DROFLU COLD may be delayed when taken together with cholestyramine (a resin that binds bile acid).
- Concomitant use with diuretic drugs (eg furosemide, thiazide) may reduce the diuretic effect and increase the risk of kidney dysfunction.

- When used together with cyclosporine and tacrolimus, which are drugs that suppress the immune system, the risk of kidney dysfunction may increase.
- When used together with mifepristone (low drug), it causes a decrease in the efficacy of mifepristone.
- May increase the risk of blood diseases when used with Zidovudine, which is effective against retroviruses including human immunodeficiency virus (HIV).
- When used together with lithium salts (used in mental illnesses), an increase in lithium blood level and related side effects may occur.
- When used together with quinolone group antibiotics (eg ciprofloxacin), the risk of severe rhythmic contraction (convulsion) in all or some of the voluntary muscles may increase.
- When used together with cardiac glycosides (eg digoxin, digitoxin) used in heart failure, these drugs may increase their blood levels by affecting their excretion from the kidneys and may cause cardiac arrhythmia.
- The risk of bleeding in the gastrointestinal tract may increase when used together with drugs that inhibit the activities of cells that mediate blood clotting (antiplatelet agents, eg aspirin, dipyridamole, clopidogrel) and selective serotonin reuptake inhibitors used for depression (eg fluoxetine, fluvoxamine, paroxetine, sertraline).
- Very rare hypoglycemia (low blood sugar) has been observed when used in combination with sulfonylurea therapy (used in the treatment of diabetes).
- Reduction of the ibuprofen dose should be considered, especially when high doses of ibuprofen are used together with drugs that inhibit CYP2C9, an enzyme that metabolizes drugs in the liver (eg voriconazole, fluconazole).
- The use of DROFLU COLD together with nasal decongestant drugs, tricyclic antidepressants (eg amitriptyline, nortriptyline, imipramine and desipramine), appetite suppressants and some nervous system stimulating drugs or MAOIs (monoamine oxidase inhibitors: moclobemide) can sometimes cause blood pressure to increase. it could be. Because the drug contains pseudoephedrine, it can partially reverse the effects of drugs that lower blood pressure, such as bretylium, betanidine, guanitidine, debrisoquine, methyldopa and alpha and beta adrenergic blockers. Concomitant use with moclobemide creates a risk of hypertensive crisis (severe blood pressure elevation).

- Use with ergot alkaloids (ergotamine and methysergite; used in the treatment of migraine) increases the risk of side effects.
- It increases the risk of hypertension with oxytocin used to facilitate delivery.
- Ibuprofen and other drugs effective for pain, fever and inflammation may reduce the effect of drugs used in the treatment of high blood pressure and increase the risk of kidney damage of ACE inhibitors used in the treatment of high blood pressure.
- When used together, DROFLU COLD may increase blood levels and unwanted side effects of methotrexate (a medicine used to treat cancer) and antidepressants (used to treat depression).

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

### **3. How to use DROFLU COLD?**

Always take this medicine as described in this leaflet or as your doctor or pharmacist has told you. If you are unsure, consult your doctor or pharmacist. Do not use this medicine for more than 10 days unless your doctor tells you otherwise.

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

In adults and children over 12 years of age, it should be taken orally as a starting dose of 2 tablets and, if necessary, 1-2 tablets every 4 hours, with some water.

Unless recommended by the physician, it should not be taken more than 6 tablets per day.

#### **Application route and method:**

DROFLU COLD tablet is taken orally with a glass of water.

#### **Different age groups:**

##### **Use in children:**

DROFLU COLD should not be used in children under 12 years of age.

For children 12 years of age and older, the adult dose is administered.

##### **Use in the elderly:**



Adult dosage is used in the elderly. It should be used with caution in patients over 60 years of age.

### **Special use cases**

#### **Kidney/Liver failure:**

The use of DROFLU COLD should be avoided in patients with severe renal and/or hepatic impairment or, if necessary, it should be used in low doses under the supervision of a physician.

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

#### **If you use more DROFLU COLD than you should:**

*If you have used more than you should use from DROFLU COLD, talk to a doctor or pharmacist.*

If you have taken more Droflu Cold Tablet than you should, or if children have used this medicine by accident, always consult a doctor or nearest hospital for advice on the action to be taken and an opinion on the risk.

Symptoms; may include nausea, abdominal pain, vomiting (may have bloody streaks), headache, tinnitus, confusion, and shaky eye movements. At high doses, drowsiness, chest pain, palpitations, unconsciousness, convulsions (especially in children), weakness and dizziness, blood in the urine, feeling cold, respiratory problems have been reported.

#### **If you forget to use DROFLU COLD:**

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

#### **Effects that may occur when treatment with DROFLU COLD is terminated:**

When DROFLU COLD treatment is terminated, no adverse effects are expected.

#### **4. What are the possible side effects?**

Like all medicines, there may be side effects in people who are sensitive to the substances contained in DROFLU COLD.

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

- Shortness of breath; swelling of the face, lips, eyelids, tongue and throat: severe itching and rash on the skin: palpitations and dizziness due to low blood pressure (Hypersensitivity – Allergy).
- Wheezing or difficulty breathing (asthma attack)
- Elevated blood pressure (hypertension)
- Irregularity in heartbeat, palpitations, chest pain
- Severe abdominal pain (stomach ulcer or pancreatitis)
- Jaundice in the eyes and skin (liver dysfunction)
- Blood in stool or vomit or black color like coffee grounds (gastrointestinal bleeding)
- Bruises on the skin, bleeding from the nose and gums, increased incidence of infectious diseases, pallor and weakness (bone marrow suppression)
- On the skin, mouth, eyes, around the genitals; severe illness with skin peeling, swelling, blisters and fever (Steven-Johnson syndrome)
- Illness in the form of accumulation of water in the mouth and other areas of the body or with red rashes of different sizes (erythema multiforme)
- A serious disease with fluid-filled blisters on the skin, skin peeling and tissue loss (toxic epidermal necrolysis)
- Sudden loss of muscle strength, loss of sensation, visual disturbances (stroke)
- Severe headache, neck stiffness, nausea, vomiting and confusion (aseptic meningitis)
- If there is a state of seeing and hearing things that are not real (hallucination)
- A severe skin reaction known as DRESS syndrome may occur. Symptoms of DRESS include: rash, fever, swelling of the lymph nodes and an increase in eosinophils (a type of white blood cell)

Medicines such as DROFLU COLD may cause a small increase in the risk of heart attack (myocardial infarction) or stroke.

These are all very serious side effects.

If you have one of these, it means you have a serious allergy to DROFLU COLD. You may need emergency medical attention or hospitalization.

These very serious side effects are very rare.

### **Other side effects:**

Other possible side effects are classified as shown in the following categories:

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

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

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

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

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

Not known : Cannot be estimated from the available data.

**Common:**

- Irritability
- Insomnia
- dizziness
- Dizziness
- dry mouth
- nausea
- Vomiting

**Uncommon:**

- Anemia
- Hives
- skin rash
- Itching
- Redness
- Facial rash
- Tiredness
- rush state
- restlessness
- Headache
- Water collection in the legs
- Abdominal and stomach pain, bloating-tension
- Indigestion
- Burning in urination
- Inability to urinate
- Hypersensitivity

**Rare:**

- Seeing or hearing things that are not real, especially in children (hallucinations)
- Personality disorder
- Increase in blood pressure
- Palpitations, rapid heartbeat
- Heart failure
- Chest pain
- Shortness of breath
- Diarrhea or constipation
- Stomach gas
- skin rash
- Allergic dermatitis (eczema)
- Other cardiac dysrhythmias (heartbeat disorders)
- Contraction of smooth muscles of the bronchi and bronchioles

**Very rare:**

- Settlement of blood on the skin, bleeding
- Decrease in the number of white blood cells
- Decrease in the number of platelets (eye and skin discoloration or yellowing, fever, sore throat, mild ulcers in the mouth, weakness, bleeding in the nose or skin)
- Inflammation of the meninges (neck stiffness, headache, nausea, vomiting, fever or loss of orientation (perception of place, time, place))
- Defect of vision
- tinnitus
- dizziness
- Gastric ulcer, perforation
- Chronic inflammation and ulceration of the large intestine and rectum
- vomiting blood
- Increased liver function tests, liver inflammation, jaundice
- Difficulty in breathing, asthma, narrowing of the bronchi
- Wheezing
- Wound in the mouth
- Inflammation with blood sitting, swelling and redness on the skin and around the eyes (Stevens-Johnson syndrome)

- Fluid-filled blisters on the skin, skin peeling and tissue loss
- Kidney failure (such as swelling in the ankles)
- Detection of blood in the urine
- Presence of protein in the urine
- Edema

**Unknown:**

- Anxiety
- Irritability (oversensitivity to stimuli)

These are mild side effects of DROFLU COLD.

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

**5. Storage of DROFLU COLD**

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

It should be stored at room temperature below 25°C.

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

*Do not use DROFLU COLD after the expiry date on the package.*

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

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*This instruction for use has been approved on 16/11/2018.*