

Read this sheet in full before using, and keep for later reference.

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BUFFERIN PREMIUM DX

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Fast, Highly Effective Pain Relief for Headaches (headache and fever)

<Pain reliever/fever reducer>

BUFFERIN PREMIUM DX

Designated Class 2 OTC drugs

Some BUFFERIN brand products contain different active ingredients. The pain relieving/fever reducing ingredients in this product are **ibuprofen** and **acetaminophen**. When consulting a doctor, dentist, pharmacist or registered seller about this product, specify that the product you are asking about contains ibuprofen and acetaminophen.

Warnings

Do not

(Failure to comply with these instructions increases the likelihood of current symptoms worsening, side effects occurring, and other potentially serious risks)

1. Do not use this product if you

- (1) Have ever had an allergic reaction to this product or any of its ingredients
- (2) Have ever had an asthma attack after using this product, any other pain reliever/fever reducer, or a cold medicine
(using the product may trigger an asthma attack)
- (3) Are under 15 years old
- (4) Are receiving medical treatment for any of the following conditions or taking any of the following pharmaceuticals: stomach or duodenal ulcers; blood disease; liver disease; kidney disease; heart disease; high blood pressure; or if you are taking zidovudine (Retrovir).

(In persons with stomach or duodenal ulcers, liver disease or kidney disease, the product may cause symptoms to worsen; in persons with blood disease, the product may cause leucocyte or platelet counts to fall, worsening symptoms; in persons with heart disease, the product may cause cardiac dysfunction to worsen; in persons with high blood pressure, the product may cause a rise in blood pressure)
- (5) Are pregnant and expecting to give birth within 12 weeks

2. Do not take any of the following pharmaceuticals while using this product

Other pain relievers/fever reducers, cold medicines, sedatives

3. Do not consume alcohol before or after taking this product

(Alcohol generally promotes drug absorption and metabolism and may cause side effects or increase toxicity, which can cause serious liver damage)

4. Do not use this product continuously for extended periods

Seek advice

1. Ask a doctor, dentist, pharmacist or registered seller before use if you are

- (1) Currently receiving treatment from a doctor or dentist
- (2) Pregnant or suspect you may be pregnant
- (3) Breast-feeding
- (4) Elderly

(The physiological functions of elderly individuals are generally reduced, which may result in stronger side effects)

- (5) Have ever shown allergic symptoms when taking a drug or medicine
- (6) Currently diagnosed with or have ever had any of the following conditions: stomach or duodenal ulcers; blood disease; kidney disease; liver disease; heart disease; high blood pressure, bronchial asthma (using the product may trigger a bronchial asthma attack); systemic erythematosus (may cause kidney disorders or other symptoms to worsen or cause aseptic meningitis); mixed connective tissue disease (may cause aseptic meningitis); ulcerous colitis; Crohn's disease (the product has been reported to cause symptoms to worsen)

2. The following symptoms may be side effects of the product. If you experience any of the following symptoms when using the product, stop use immediately and bring this sheet to a doctor, dentist, pharmacist or registered seller for consultation.

Affected area	Symptom
Skin	Rash or redness; itchiness; bruising
Digestive tract	Nausea or vomiting; loss of appetite; stomach discomfort; stomach pain; oral inflammation; heartburn; heaviness in the stomach; gastrointestinal bleeding; abdominal pain; diarrhea; bloody stool
Mental state / Nervous system	Dizziness, drowsiness, insomnia, feelings of sadness
Circulatory system	Heart palpitations
Respiratory system	Shortness of breath
Other	Blurred vision; ringing in the ears; swelling; nosebleed; bleeding from the gums; bleeding that does not stop; bleeding; back pain; excessive drop in body temperature; lethargy

The following rare but serious conditions may also occur. If you experience any of the symptoms below, seek immediate medical attention from a doctor.

Condition	Symptoms
Shock (anaphylaxis)	The following symptoms occur shortly after use: itchy skin; hives; hoarse voice; sneezing; itchy throat; difficulty breathing; heart palpitations; feeling faint
Mucocutaneous ocular syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, acute generalized exanthematous pustulosis	Persistence or sudden worsening of: severe fever; bloodshot eyes; eye mucus; lip sores; sore throat; widespread rash or skin redness; small pimples (pustules) appear on reddened skin; overall lethargy; loss of appetite

Drug-induced hypersensitivity syndrome	Widespread skin redness; systemic rash; fever; lethargy; swelling of lymph nodes (in the neck, armpits, groin, etc.)
Digestive disfunction	Black stool; vomiting blood; bloody stool; mucus and blood in stool (loose stool mixed with blood, mucus or pus)
Impaired liver function	Fever; itchiness; rash; jaundice (skin and whites of the eyes appear yellowish); brown urine; overall lethargy; loss of appetite
Kidney disorder	Fever; rash; reduced urine output; swelling all over the body; overall lethargy, arthralgia (joint pain); diarrhea
Aseptic meningitis	Severe headache accompanied by neck stiffness; fever; nausea or vomiting (these symptoms are especially common in patients receiving care for systemic erythematous or mixed connective-tissue disease)
* <u>Myocardial infarction (heart attack)</u>	<u>Pressure-like chest pain; shortness of breath; cold sweat</u>
* <u>Cerebrovascular disease (stroke)</u>	<u>Sudden onset of decreased or loss of consciousness; weakness moving one side of the body; headache; vomiting, dizziness; difficulty speaking</u>
Interstitial pneumonia	Sudden onset or persistence of: shortness of breath or difficulty breathing after mild exertion, such as when climbing stairs; dry coughing; fever
Asthma	Wheezing or gasping for breath, difficulty breathing
Aplastic anemia	Bruising; nosebleed; bleeding from the gums; fever; skin and mucous membranes appear pale; fatigue; heart palpitations; shortness of breath; feeling sick and dizziness; bloody urine
Agranulocytosis	Sudden onset of fever, chills or sore throat

- 3. The following symptoms may occur during use. If these symptoms persist or worsen, stop use and bring this sheet to a doctor, pharmacist or registered seller for consultation.**

Constipation; dry mouth

- 4. During use, a drop in body temperature below regular temperature, muscle weakness (collapse), coldness in the limbs, or other symptoms may occur. If you experience any of these symptoms, stop use immediately, use blankets or other means to stay warm, and bring this sheet to a doctor, pharmacist or registered seller for consultation.**
- 5. If symptoms do not improve after 3 or 4 doses, stop use and bring this sheet to a doctor, dentist, pharmacist or registered seller for consultation.**

Effects

(1) Pain relieving effect on headache, pain due to stiff shoulders, menstrual pain, back pain, joint pain, neuralgia, muscle pain, sore throat, toothache, pain after tooth extraction, pain from bruising, pain from sprains, pain from bone fractures, pain from trauma and earache. (2) Reducing effect on chills and fevers

Directions and Dosage

Avoid taking on an empty stomach and wait at least four hours between doses.

Take the following amount with lukewarm or cold water.

Age	Adults (15 years and up)	Children under 15 years
Amount per 1 dose	2 tablets	Do not use x
Doses per day	No more than 2 However, a third dose can be taken if symptoms return.	

Usage and Dosage Warnings

- (1) Use only as directed.
- (2) To remove the tablets from the package: As shown in the illustration on the right, press firmly with a fingertip on the protruding bubble in the clear plastic sheet that contains the tablet, pushing the tablet through the foil backing and out (swallowing the product without first removing it from the package can lead to injury, such as damage to the esophageal membrane).



Ingredients (per 2 tablets)

Active ingredient	Content	Purpose
Ibuprofen	160 mg	Reduces pain and fever
Acetaminophen	160 mg	
Anhydrous caffeine	50 mg	Boosts pain relief effect, eases headache
Dehydrated aluminum hydroxide gel	70 mg	Protects the gastric mucosa, helps prevent stomach problems

Inactive ingredients: cellulose, hydroxypropylcellulose, lactic acid, D-mannitol, potassium dihydrogenphosphate, silicon dioxide, magnesium stearate, polyvinyl alcohol (partially saponified), talc, titanium oxide, glycerol fatty acid ester and sodium lauryl sulfate.

Storage and Handling

- (1) Store out of direct sunlight in a cool, dry place.
- (2) Keep out of reach of children.
- (3) Do not transfer to another container or package (may lead to incorrect use or affect product quality).
- (4) Do not use after the use-by date indicated on the package.
- (5) Avoid damaging the foil protecting tablets you are not planning to use immediately, as exposure can affect product quality.

Inquiries

Please direct inquiries to the store where you purchased the product or the service center below.

Lion Corporation Consumer Service Center 0120-813-752

Hours available: 9:00–17:00 (excluding Saturdays, Sundays and holidays)

Lion Corporation

1-3-28 Kuramae, Taito-ku, Tokyo 111-8644

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