IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

APO-IBUPROFEN 200 mg
Ibuprofen Tablets USP, 200 mg

APO-IBUPROFEN Caplet
Ibuprofen Tablets USP, 200 mg

APO-IBUPROFEN 300 mg
Ibuprofen Tablets USP, 300 mg

APO-IBUPROFEN 400 mg
Ibuprofen Tablets USP, 400 mg

APO-IBUPROFEN Caplet
Ibuprofen Tablets USP, 400 mg

This leaflet is part III of a three-part "Product Monograph" published when APO-IBUPROFEN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-IBUPROFEN. Contact your physician or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Since everyone's pain is different, APO-IBUPROFEN offers 3 levels of pain relief to suit your needs. So you can choose your relief, APO-IBUPROFEN products are available in three strengths, including APO-IBUPROFEN 200 mg (Regular Strength), APO-IBUPROFEN 300 mg and APO-IBUPROFEN 400 mg (Extra Strength) Tablets.

APO-IBUPROFEN products provide fast and effective relief of PAIN from:

- headache, including mild to moderate migraine and tension headache
- menstrual cramps
- toothache (dental pain), including dental extraction
- inflammation from arthritis, muscle strain, and sprains, muscles, bones and joints, including back pain

APO-IBUPROFEN is also an effective fever reducer and will provide relief from the aches and pain due to the common cold and flu.

Clinical studies show long lasting relief for up to 8 hours for fever and up to 6 hours for pain.

What it does:

APO-IBUPROFEN ibuprofen starts to work fast and treats pain where it starts.

Ibuprofen is a member of a class of drugs called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work within the body by blocking the production of substances, called prostaglandins, which are involved in the development of pain and inflammation.

When it should not be used:

APO-IBUPROFEN should not be used if you:

- are taking acetylsalicylic acid (ASA) or any other non-steroidal anti-inflammatory medication, including any other ibuprofen product.
- are allergic or have had a reaction to ibuprofen, acetylsalicylic acid (ASA), other non-steroidal anti-inflammatory drugs (NSAIDs) or salicylates, or to any ingredient in the formulation (see non-medicinal ingredients below). Allergic reactions may appear as hives, difficulty breathing, rash, swelling of the face or throat or sudden collapse.
- have nasal polyps (swelling of the inside of the nose), or allergic manifestations such as asthma, anaphylaxis (sudden severe life-threatening anaphylactic reactions), urticaria/hives, rhinitis (stuffed or runny nose that may be due to allergies), skin rash or other allergic symptoms.
- **have been diagnosed with severe high blood pressure or have severe coronary artery disease.**
- are dehydrated (significant fluid loss) due to vomiting, diarrhea or lack of fluid intake.
- have active or recurrent stomach ulcer, gastrointestinal (GI) bleeding, or active inflammatory bowel disease (e.g. Crohn's, colitis)
- have liver or kidney disease.
- have systemic lupus erythematosus.
- are pregnant or nursing, unless advised otherwise by a physician.

What the medicinal ingredient is:

Ibuprofen

What the important nonmedicinal ingredients are:

APO-IBUPROFEN 200 mg is a yellow, round,

biconvex film-coated tablet, engraved "IBU" over "200" on one side, plain on the other. APO-IBUPROFEN 200 mg is yellow, capsule-shaped, biconvex film-coated tablet engraved "200" on one side and "IBU" on the other. APO-IBUPROFEN 200 mg tablets and caplets contain: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C Yellow No. 10, FD&C Yellow No. 6, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

APO-IBUPROFEN 200 mg is a reddish-brown, round, biconvex film-coated tablet engraved "IBU" over "200" on one side, plain on the other. APO-IBUPROFEN is a reddish-brown, capsule-shaped, biconvex film-coated tablet engraved "200" on one side and "IBU" on the other side. APO-IBUPROFEN 200 mg tablets and caplets contain: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, red ferric oxide, titanium dioxide.

APO-IBUPROFEN 300 mg is a white, round, biconvex film-coated tablet engraved "APO" over "300" on one side, plain on the other. APO-IBUPROFEN 300 mg tablets contain: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

APO-IBUPROFEN 400 mg is an orange, round, biconvex film-coated tablet engraved "IBU" over "400" on one side, plain on the other side. APO-IBUPROFEN 400 mg tablets contain: colloidal silicon dioxide, croscarmellose sodium, FD&C Yellow No. 6 hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

APO-IBUPROFEN 400 mg is a reddish-brown, capsule shaped, biconvex film-coated tablet engraved "IBU 400" on one side, plain on the other. APO-IBUPROFEN 400 mg caplet contain: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, red ferric oxide, titanium dioxide.

What dosage forms it comes in:

Tablets: 200 mg, 300 mg, 400 mg
Caplets: 200 mg, 400 mg

WARNING AND PRECAUTIONS

Serious Warning and Precautions
Caution in patients prone to gastrointestinal tract irritation, including those with a history of peptic ulcer.

BEFORE you use APO-IBUPROFEN talk to your physician or pharmacist if you:

- have stomach ulcers, high blood pressure, asthma, heart failure, kidney or liver disease, diabetes, alcoholism, a history of stomach bleeding, systemic lupus erythematosus, or any other serious disease or condition.
- are taking anticoagulant (blood thinning medication), oral corticosteroid or any other drug.
- are nursing an infant.
- are over 65 years of age.
- are taking low-dose ASA.
- suffer from asthma or have nasal polyps (a swelling inside the nose).
- are dehydrated (severe fluid loss).
- have a blood-clotting disorder (e.g. hemophilia, sickle cell anemia, etc.).
- have a heart disease.
- have any unusual urinary symptoms (e.g. bladder problems).
- are on a special diet (e.g. low-sodium).
- suffer from hyperkalemia (high levels of potassium in your blood).

They may recommend an alternative analgesic such as acetaminophen.

INTERACTIONS WITH THIS MEDICATION

Always tell any physician, dentist, or pharmacist you consult that you are taking this medicine.

Drugs that may interact with APO-IBUPROFEN include: acetylsalicylic acid (ASA) or other NSAIDs, blood thinning medications (anticoagulants), blood pressure medication (anti-hypertensives), diuretics (water pills), oral steroids (glucocorticoids), lithium, diabetes medications (hypoglycemics), methotrexate, phenytoin, acetaminophen and digoxin.

Do not use this product if you are taking daily low dose ASA (81-325 mg) without talking to a physician or pharmacist. Ibuprofen may interfere with the preventative benefits of ASA.

PROPER USE OF THIS MEDICATION

Usual dose:
For accurate dosing of each product strength, refer to the dosage table and follow the instructions carefully.

PRODUCT	STRENGTH (IBUPROFEN MG/TABLET)	SINGLE ORAL DOSE	MAXIMUM DAILY DOSE (1200 MG)
(Regular Strength) APO-IBUPROFEN 200 mg; APO-IBUPROFEN Caplet	200 mg	1 or 2 tablets	6 tablets
APO-IBUPROFEN 300 mg	300 mg	1 tablet	4 tablets
(Extra Strength) APO-IBUPROFEN 400 mg APO-IBUPROFEN Caplet	400 mg	1 tablet	3 tablets

The single oral dose may be taken every 4-6 hours as needed. Do not take more than the maximum daily dose (1200 mg in 24 hours) unless advised by a physician. Take with food or milk if mild stomach upset occurs with use, APO-IBUPROFEN should not be taken for pain for more than 5 consecutive days or for fever for more than 3 days without first talking to your physician or dentist.

Do not take this product while taking ASA, other ibuprofen containing products or any other pain or fever medicine.

For effective use of this medicine, unless recommended by your physician or dentist, DO NOT take:

- more than the recommended number of tablets, caplets in each single dose
- a dose more often than every 4-6 hours
- this product longer than the recommended period of time
- more than the smallest dose that will relieve your symptoms

Overdose:

In case of overdose, even if there are no symptoms, call a physician or Poison Control Centre at once.

Missed Dose:

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take your medicine and skip the missed dose. Do not take two doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If unusual symptoms or any of the following reactions develop during treatment, stop use and see a physician immediately: nausea, vomiting, abdominal pain or diarrhea; heartburn, bloating or constipation; fluid retention; skin rash or itching; dizziness; any change in vision; ringing or buzzing in the ears, vomiting any blood or have tarry stools, jaundice (yellowing of the eyes or skin due to liver problems).

If you experience dizziness, blurred vision, or hearing problems while taking APO-IBUPROFEN, please use caution when carrying out activities requiring alertness.

Ibuprofen may cause a severe allergic reaction that could include wheezing, facial swelling, hives, shortness of breath, shock or a fast, irregular heartbeat. Any of these reactions could be serious. Stop using the product and get emergency medical help immediately.

This is not a complete list of side effects. For any unexpected effects while taking APO-IBUPROFEN, contact your physician or pharmacist.

HOW TO STORE IT

Store at room temperature (15°C to 30°C).

REPORTING SUSPECTED SIDE EFFECTS
You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your physician, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at:

http://www.apotex.ca/prodcuts.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9

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