

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74931

DRAFT FINAL PRINTED LABELING

CONSUMER LABELING LEAFLET FOR IBUPROFEN TABLETS USP, 200 mg

PLEASE SAVE THIS FOR FUTURE USE.

Only selected information is contained on the bottle label.
Therefore, you should keep this sheet for future reference.

IBUPROFEN TABLETS USP, 200 mg (Tablets / Caplets*) (*capsule-shaped tablets)

Pain Reliever / Fever Reducer

WARNING: ASPIRIN SENSITIVE PATIENTS. Do not take this product if you have had a severe allergic reaction to aspirin, e.g. - asthma, swelling, shock or hives, because even though this product contains no aspirin or salicylates cross-reactions may occur in patients allergic to aspirin.

INDICATIONS: For the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps and for reduction of fever.

DIRECTIONS: Adults: Take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not exceed 6 tablets in 24 hours, unless directed by a doctor. The smallest effective dose should be used. Take with food or milk if occasional and mild heartburn, upset stomach, or stomach pain occurs with use. Consult a doctor if these symptoms are more than mild or if they persist. **Children:** Do not give this product to children under 12 except under the advice and supervision of a doctor.

WARNINGS: Do not take for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if the painful area is red or swollen, consult a doctor. These could be signs of serious illness. If you are under a doctor's care for any serious condition, consult a doctor before taking this product. As with aspirin and acetaminophen, if you have any condition which requires you to take prescription drugs or if you have had any problems or serious side effects from taking any non-prescription pain reliever, do not take Ibuprofen Tablets without first discussing it with your doctor. If you experience any symptoms which are unusual or seem unrelated to the condition for which you took ibuprofen, consult a doctor before taking any more of it. Although ibuprofen is indicated for the same conditions as

aspirin and acetaminophen, it should not be taken with them except under a doctor's direction. Do not combine this product with any other ibuprofen-containing product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. **IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.** Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

ALCOHOL WARNING: If you generally consume 3 or more alcohol-containing drinks per day, you should consult your physician for advice on when and how you should take IBUPROFEN and other pain relievers.

Store at room temperature. Avoid excessive heat 40°C (104°F).

Active Ingredient: Each tablet contains Ibuprofen USP 200 mg.

Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, lactose monohydrate, maltodextrin, microcrystalline cellulose, polydextrose, polyethylene glycol, sodium lauryl sulfate, stearic acid, synthetic red iron oxide, synthetic yellow iron oxide, talc, titanium dioxide and triacetin.

Distributed by: Granutec, Inc.
Wilson, N.C. 27896

Made in Canada

80953IN

Issued April 1997
Sub. 00

NDC 55953-160-80

IF PRINTED FOIL SEAL UNDER CAP IS BROKEN OR MISSING WHEN PURCHASED, DO NOT USE.

Ibuprofen Tablets, USP

Pain reliever / Fever reducer
Pain Relief Formula

1000 Coated Caplets*
200 mg each
*Capsule-shaped tablets

novopharm



Sub. 00
Keep this and all other parts of the pack of children. In case of accidental ingestion, seek professional assistance or contact a poison control center for complete information.
WARNING: See consumer advice for complete information.
ADVERSE REACTIONS: Each caplet contains ibuprofen USP 200 mg.
CONTRAINDICATIONS: Do not use if you are allergic to ibuprofen or any of the other ingredients.
CAUTIONS: Do not use if you are pregnant or nursing a baby. See the advice of a health professional before using the product.
PREGNANT WOMEN SHOULD NOT USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIALLY INSTRUCTED BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD ON ALCOHOL. WARNING: If you generally consume 3 or more alcohol-containing drinks per day, you should consult your physician for advice on when and how you should take IBUPROFEN and other pain relievers.

Area for Lot and Exp.

NDC 55953-160-80

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Area for Lot and Exp.

IBUPROFEN Tablets, USP

Pain reliever / Fever reducer

Pain Relief Formula

Non-Prescription Strength

IBUPROFEN Tablets, USP

Pain reliever / Fever reducer
Pain Relief Formula

100 Coated Tablets
200 mg each

novopharm[®]



Do not use if carton is open, or if printed foil seal under cap is broken or missing when purchased.

READ CONSUMER LEAFLET BEFORE USE.

LOT
EXP.

IBUPROFEN TABLETS, USP Pain Reliever / Fever Reducer

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WARNINGS (CONTINUED)

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Distributed by: Granulec, Inc., Wilson, N.C. 27896
Made in Canada
80953CT-5840

Sub. 00

Ibuprofen Tablets, USP

Pain reliever / Fever reducer

Pain Relief Formula

Do not use if carton is open, or if printed foil seal under cap is broken or missing when purchased.

READ CONSUMER LEAFLET BEFORE USE.

152

IBUPROFEN Tablets, USP

Pain reliever / Fever reducer
Pain Relief Formula



Non-Prescription Strength

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

IBUPROFEN Tablets, USP

Pain reliever / Fever reducer
Pain Relief Formula
72 Coated Caplets*
200 mg each
*Capsule-shaped tablets

novopharm[®]

APR 20 1996



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LOT
EXP.

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WARNINGS (CONTINUED)

Caplets* (*capsule-shaped tablets) without first discussing it with your doctor. If you experience any symptoms which are unusual or seem unrelated to the condition for which you took ibuprofen, consult a doctor before taking any more of it. Although ibuprofen is indicated for the same conditions as aspirin and acetaminophen, it should not be taken with them except under a doctor's direction. Do not combine this product with any other ibuprofen-containing product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. **IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.** Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

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