CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-010

***Name*:** Ibuprofen Tablets USP, 200 mg
(round and capsule shaped tablets, colored brown)

***Sponsor*:** LNK International, Inc.

***Approval Date*:** March 1, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010

APPROVAL LETTER

ANDA 75-010

MAR 1 1999

LNK International, Inc.
Attention: Pankaj S. Chudgar
60 Arkay Drive
Hauppauge, NY 11788

Dear Sir:

This is in reference to your abbreviated new drug application dated November 27, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ibuprofen Tablets USP, 200 mg (round and capsule shaped tablets, colored brown).

Reference is also made to your amendments dated April 10, and August 1, 1997; March 5, August 10, August 14, and December 21, 1998; and January 4, January 19, and February 10, 1999.

We have completed the review of this abbreviated application and have concluded that the drug product is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined that your Ibuprofen Tablets 200 mg (round and capsule shaped tablets, colored brown) are bioequivalent to the listed drug product upon which the Agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

D. L. Sporn 3/1/99

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-010
Division File
FIELD COPY
HFD-610/RLWest
HFD-92
HFD-210/B.Poole
HFD-330/
HFD-205/

Endorsements:
HFD-623/U.Atwal/ U.Atwal 2/8/99
HFD-623/V.Sayeed/2-2-99 V. Sayeed 2/9/99.
HFD-617/M.Anderson, PM/2-2-99 Mark Anderson 2/9/99
HFD-613/J.Barlow/J.Grace for/2-5-99
HFD-613/J.Grace 2/9/99

X:\new\firmsam\lnk\ltrs&rev\75010.apd
F/T by: bc/2-8-99

APPROVAL
Revised per cc'd 2/24/99 (new addendum)

2/24/99

Robert Lewis
3/1/99

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010

LABELING

B16415

EXPIRATION DATE

LOT NO.

0 50844-292-02 4

QUALITY PLUS

NDC 50844-292-02

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

12 Film Coated Brown Caplets*, 200 MG EACH

*Caplets (Capsule-shaped Tablets)

QUALITY PLUS

NDC 50844-292-02

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

12 Film Coated Brown Caplets*, 200 MG EACH

*Caplets (Capsule-shaped Tablets)

QUALITY PLUS

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

12 Film Coated Brown Caplets*, 200 MG EACH

*Caplets (Capsule-Shaped Tablets)

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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

ACTIVE INGREDIENT: Each tablet contains ibuprofen USP, 200 mg.

INACTIVE INGREDIENTS: Cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, synthetic red iron oxide, titanium dioxide, and triacetin.

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 a 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 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.

Made in USA 50844 ORG 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788

dg99

98-81 Ibup. 12 Cplt. BX, DG 99, 08/06/98, MAC 8500, Process Yellow, Process, Blue, PMS 485, Black. LNK/Quality Plus. Rev,10/29/98.

B16501

LOT NO.

EXPIRATION DATE

0 50844-292-13 0

QUALITY PLUS

NDC 50844-292-13

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

250 Film Coated Brown Caplets*, 200 MG EACH

*Caplets (Capsule-shaped Tablets)

QUALITY PLUS

NDC 50844-292-13

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

250 Film Coated Brown Caplets*, 200 MG EACH

*Caplets (Capsule-shaped Tablets)

QUALITY PLUS

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

250 Film Coated Brown Caplets*, 200 MG EACH

*Caplets (Capsule-Shaped Tablets)

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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.

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

ACTIVE INGREDIENT: Each tablet contains Ibuprofen USP, 200 mg.

INACTIVE INGREDIENTS: Cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, synthetic red iron oxide, titanium dioxide and triacetin.

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 a 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 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.

Made in USA 50844 ORG 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788

dg9821

QUALITY PLUS NDC 50844-292-02

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

12 Film Coated Brown Caplets*, 200 MG EACH

***Caplets (Capsule-Shaped Tablets)**

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 a 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 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).**

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

ACTIVE INGREDIENT: Each tablet contains ibuprofen USP, 200 mg. **INACTIVE INGREDIENTS:** Cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, synthetic red iron oxide, titanium dioxide, and triacetin.

Made in USA 50844 ORG 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788

IBUPROFEN TABLETS 200mg. CAPSULE SHAPED FILM COATED BROWN 12 COUNT, ACTUAL LABELING

QUALITY PLUS NDC 50844-292-02

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

12 Film Coated Brown Caplets*, 200 MG EACH

***Caplets (Capsule-Shaped Tablets)**

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 a 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 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).**

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

ACTIVE INGREDIENT: Each tablet contains ibuprofen USP, 200 mg. **INACTIVE INGREDIENTS:** Cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, synthetic iron oxide, titanium dioxide, and triacetin.

Made in USA 50844 ORG 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788

MAR 1 1996

ENLARGED TO 150%
BY FDA STAFF

QUALITY PLUS

NDC 50844-292-12

Pain Relief Formula

IBUPROFEN

Tablets USP, 200 mg

Pain Reliever • Fever Reducer

100 FILM COATED BROWN CAPLETS*

200 MG EACH

*Caplets (Capsule-Shaped Tablets)

PACKAGE NOT CHILD RESISTANT

EASY OPEN

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 a 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 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).

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

ACTIVE INGREDIENT: Each tablet contains ibuprofen USP, 200 mg. **INACTIVE INGREDIENTS:** Cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, synthetic red iron oxide, titanium dioxide, and triacetin. Made in USA 50844 ORG 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788

0 50844-292-12 3

98-505 Ibup. 100 Br. C Lbl., 4.375" 1.375", ~~12/16~~/98, Mac 8500, PMS 485, Process Blue, Process Yellow, Black. LNK/Quality Plus.

IBUPROFEN TABLETS 200 mg. CAPSULE SHAPED FILM COATED BROWN 100 COUNT, ACTUAL LABELING

QUALITY PLUS

NDC 50844-292-12

Pain Relief Formula

IBUPROFEN

Tablets USP, 200 mg

Pain Reliever • Fever Reducer

100 FILM COATED BROWN CAPLETS*

200 MG EACH

***Caplets (Capsule-Shaped Tablets)**

PACKAGE NOT CHILD RESISTANT

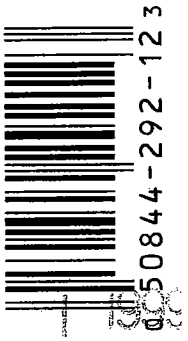
EASY OPEN

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 a 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 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).

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

ACTIVE INGREDIENT: Each tablet contains ibuprofen USP, 200 mg. **INACTIVE INGREDIENTS:** Cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, synthetic red iron oxide, titanium dioxide, and triacetin. Made in USA 50844 1098 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788



Margo

IBUPROFEN TABLETS 200mg. CAPSULE SHAPED FILM COATED BROWN 250 COUNT, ACTUAL LABELING

QUALITY PLUS

NDC 50844-292-13

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

250 Film Coated Brown Caplets*, 200 MG EACH

***Caplets (Capsule-Shaped Tablets)**

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 a 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 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).

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Made in USA 50844 ORG 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788

Mango

98-81 Ibup. 12 Cplt. BX, DG 99, 08/06/98, MAC 8500, Process Yellow, Process, Blue, PMS 485, Black. LNK/Quality Plus. Rev,10/29/98.

Mango

98-490 Ibup. 250 Br. C Lbl 12/18/98 4:17 PM Page 1

QUALITY PLUS

NDC 50844-292-13

Pain Relief Formula

IBUPROFEN Tablets USP, 200 mg

Pain Reliever • Fever Reducer

250 Film Coated Brown Caplets*, 200 MG EACH

***Caplets (Capsule-Shaped Tablets)**

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 a 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 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).

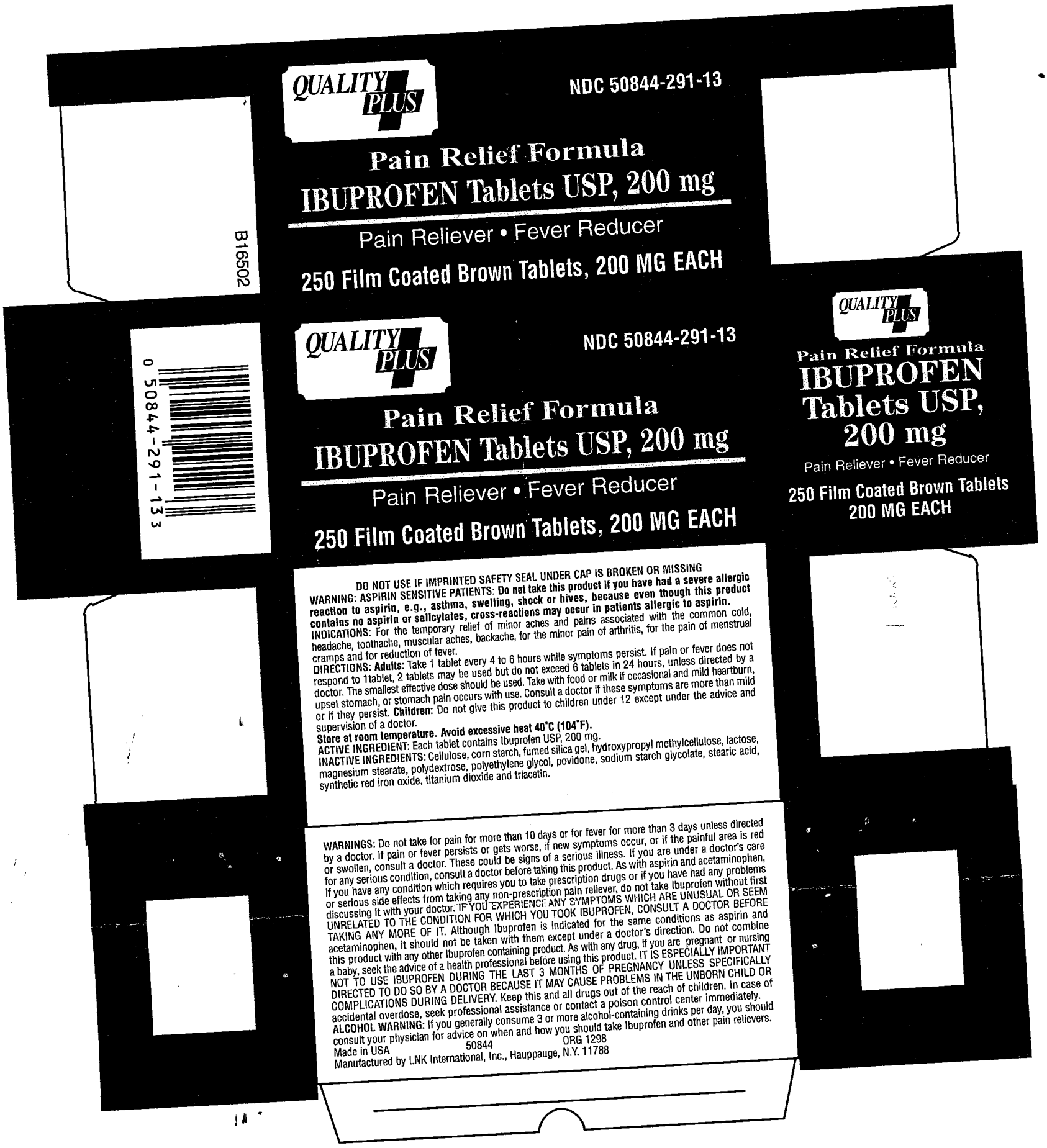
DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

ACTIVE INGREDIENT: Each tablet contains Ibuprofen USP, 200 mg. **INACTIVE INGREDIENTS:** Cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, synthetic red iron oxide, titanium dioxide and triacetin.

Made in USA 50844 ORG 1298

Manufactured by LNK International, Inc., Hauppauge, N.Y. 11788

98-490 Ibup. 250 Cplt. Lbl., 6" x 2", 12/16/98, Mac 8500, Process Yellow, Process Blue, PMS 485, Black. LNK/Quality Plus.


QUALITY PLUS
NDC 50844-291-13
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