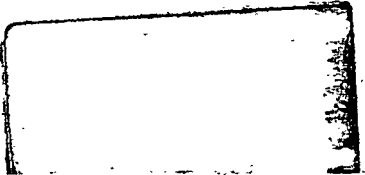


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75661

DRAFT FINAL PRINTED LABELING



IBU[®]

(Ibuprofen Tablets,
USP)

200 mg each

Pain Reliever/ Fever
Reducer

Do not use if seal around
bottle cap is missing or broken

100 COATED
TABLETS

Mfg. by BASF Corporation
Mount Olive, NJ 07828

Drug Facts	Drug Facts (continued)
Active ingredient (in each tablet) Ibuprofen 200 mg Pain reliever/fever reducer <p>Purposes</p>	<p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ headache ■ muscular aches ■ minor pain of arthritis ■ toothache ■ backache ■ the common cold ■ menstrual cramps ■ temporarily reduces fever 	<p>Directions</p> <ul style="list-style-type: none"> ■ do not take more than directed ■ adults and children 12 years and older: <ul style="list-style-type: none"> ■ 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 ■ do not exceed 6 tablets in 24 hours, unless directed by a doctor ■ the smallest effective dose should be used ■ children under 12 years: ask a doctor
<p>Warnings</p> <p>Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock <p>Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.</p>	<p>Other information</p> <ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>	<p>Inactive ingredients: Carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FDC Yellow No. 6, FDC Yellow No. 10, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, synthetic red iron oxide, titanium dioxide.</p>
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ stomach pain ■ problems or serious side effects from taking pain relievers or fever reducers 	<p>Questions or comments? Call toll free 1-800-325-0791</p>
<p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ■ under a doctor's care for any serious condition ■ taking any other drug ■ taking any other product that contains ibuprofen, or any other pain reliever/fever reducer 	<p>LOT</p> <p>EXP</p> <p style="font-size: 2em; text-align: center;">SAMPLE</p>
<p>When using this product take with food or milk if stomach upset occurs</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ an allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms appear 	

DEC 12 2007

APPROVED



IBU[®] APPROVED

(Ibuprofen Tablets, USP)

DEC 12 2001

200 mg each

Pain Reliever/ Fever Reducer

5,000 Tablets

Safety seal: Do not use
if carton is open

<i>Drug Facts</i>	<i>Drug Facts(continued)</i>
Active ingredient (in each tablet) Ibuprofen 200 mg.....Pain reliever/fever reducer	If pregnant or breast-feeding , ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Uses ■ temporarily relieves minor aches and pains due to: ■ headache ■ muscular aches ■ minor pain of arthritis ■ toothache ■ backache ■ the common cold ■ menstrual cramps ■ temporarily reduces fever	
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Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer	
Ask a doctor before use if you have ■ stomach pain ■ problems or serious side effects from taking pain relievers or fever reducers	Other information ■ store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious condition ■ taking any other drug ■ taking any other product that contains ibuprofen, or any other pain reliever/fever reducer	Inactive ingredients: Carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FDC Yellow No. 6, FDC Yellow No. 10, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, synthetic red iron oxide, titanium dioxide.
When using this product take with food or milk if stomach upset occurs	Questions or comments? Call toll free 1-800-325-0791
Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms appear	Mfg by: BASF Corporation Mount Olive, NJ 07828 SAMPLE 01-12345

Repackager Caution:

Expiration date listed applies to expiration in bulk configuration
Expiration dating applied to repackaged product should comply
With USP <1191> or FDA guidance for repackaging

IBU[®]

(Ibuprofen Tablets, USP)

200 mg each

Pain Reliever/ Fever Reducer

50,000 Tablets

APPROVED

DEC 12 2007

Safety seal: Do not use if carton is open

<i>Drug Facts</i>	<i>Drug Facts(continued)</i>
Active ingredient (in each tablet) Ibuprofen 200 mg.....Pain reliever/fever reducer	Purposes Pain reliever/fever reducer
Uses ■ temporarily relieves minor aches and pains due to: ■ headache ■ muscular aches ■ minor pain of arthritis ■ toothache ■ backache ■ the common cold ■ menstrual cramps ■ temporarily reduces fever	If pregnant or breast-feeding , ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
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Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious condition ■ taking any other drug ■ taking any other product that contains ibuprofen, or any other pain reliever/fever reducer	Questions or comments? Call toll free 1-800-325-0791
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SAMPLE

01-12348

Repackager Caution:

Expiration date listed applies to expiration in bulk configuration
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With USP <1191> or FDA guidance for repackaging