

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75588

DRAFT FINAL PRINTED LABELING

CUSTOMER SALES MRKTG REG-1 REG-2 DISCR UPDATE FINAL

Uses
Temporarily relieves these symptoms associated with the common cold, sinusitis, or flu:
■ headache ■ fever ■ nasal congestion ■ minor body aches and pains

Active Ingredients (in each tablet)
Ibuprofen 200 mg
Pseudoephedrine HCl 30 mg
Pain reliever/fever reducer
Nasal decongestant

Purpose

Drug Facts

200 mg
30 mg

bupropfen
and
Pseudoephedrine HCl
Tablets USP

For relief of nasal congestion, sinus pain, and fever.

20 Tablets

Manufactured by: Pharmaceutical Formulations, Inc. Edison, NJ 08818

DO NOT USE IF THE SEALED IMPRINTED BUSTER BACKS HAVE BEEN OPENED.

LOT: _____

EXP: _____


Drug Facts (continued)

Other information

- Store at 20-25 °C (68-77 °F). Avoid excessive heat above 40 °C (104 °F).
- See all warnings and directions before use. Keep carton.

Inactive ingredients
cellulose, croscarmellose sodium, hydroxypropyl methylcellulose, iron oxide, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

22450F
S200
BX3836F GF ER U




3 0916-550-200

Directions
Drug Facts (continued)

adults and children 12 years of age and over:
■ take 1 tablet every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 tablet, 2 tablets may be used.
■ do not use more than 6 tablets in any 24-hour period unless directed by a doctor.
■ the smallest effective dose should be used.
■ children under 12 years of age: consult a doctor.

1212550206



Warnings
Drug Facts (continued)

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:
■ hives ■ facial swelling ■ asthma (wheezing) ■ shock
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.

Do not use if you:
■ have ever had an allergic reaction to any other pain reliever/fever reducer
■ are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before using this product.

Ask a doctor before use if you have:
■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ stomach pain
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are:
■ taking any other product that contains ibuprofen or pseudoephedrine
■ under a doctor's care for any continuing medical condition
■ taking any other pain reliever/fever reducer or nasal decongestant
■ taking other drugs on a regular basis

When using this product:
■ do not use more than directed
■ take with food or milk if stomach upset occurs

Stop use and ask a doctor if:
■ an allergic reaction occurs. Seek medical help right away.
■ nasal congestion lasts for more than 7 days
■ symptoms continue or get worse
■ stomach pain occurs with use of this product or if even mild symptoms persist

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use this product during the last 3 months of pregnancy unless 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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Proof Approval Approved with Changes Reproof Required <input type="checkbox"/>	Customer Signature: _____	Date: _____	PFI Code: xxxc-22450F-S020	Colors:		
	UPC: _____		Name: Ibuprofen Cold & Sinus Tablets x 20	PMS #	PMS #	PMS #
	Item #: _____		Part#: BX3836F GF ER U	PMS #	PMS #	PMS #
	NDC: _____		Dimensions: 2-7/8" x 13-1/16" x 4-7/16"	PMS #	PMS #	PMS #
Artist: _____		Proof Size: 100%	IT5: 1212550206	PMS #	PMS #	DIE LINE



CUSTOMER SALES MRKTG REG-1 REG-2 DISCR UPDATE FINAL

DO NOT USE IF THE SEALED IMPRINTED BLISTER BACKS HAVE BEEN OPENED.

LOT: _____

EXP: _____

HealthPharm

Ibuprofen and Pseudoephedrine HCl

Tablets USP

Pain Reliever/Fever Reducer • Nasal Decongestant

For relief of:

- nasal congestion
- sinus pain
- fever

without drowsiness

20 Coated Caplets*

*Oval-Shaped Tablets

Drug Facts (continued)

Other Information

store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).

Read all warnings and directions before use. Keep carton.

Inactive Ingredients

carboxymethylcellulose, iron dextran sulfate, polyethylene glycol, polysorbate 80, polybutyl methacrylate, stearic acid, titanium dioxide, hydroxypropyl methylcellulose, iron dextran sulfate, polyethylene glycol, polysorbate 80, hydroxypropyl methylcellulose, iron dextran sulfate, polyethylene glycol, polysorbate 80, hydroxypropyl methylcellulose, iron dextran sulfate.

22453F
S020
BX3836F GF ER U

3 N

10916 - 453-20



Drug Facts (continued)

Directions

adults and children 12 years of age and over:
 take 1 caplet every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 caplet, 2 caplets may be used.
 do not use more than 6 caplets in any 24-hour period unless directed by a doctor.

children under 12 years of age: consult a doctor.

1212453206



Drug Facts (continued)

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock.

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.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer, or are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have heart disease, high blood pressure, thyroid disease, diabetes, stomach pain, trouble urinating due to an enlarged prostate gland, or are taking any other product that contains ibuprofen or pseudoephedrine.

When using this product:

- ask a doctor's care for any continuing medical condition
- take with food or milk if stomach upset occurs
- do not use more than directed

Stop use and ask a doctor if:

- an allergic reaction occurs. Seek medical help right away.
- nasal congestion lasts for more than 7 days
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If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use this product 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 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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<p>Proof Approval <input type="checkbox"/></p> <p>Approved with Changes <input type="checkbox"/></p> <p>Reproof Required <input type="checkbox"/></p>	<p>Customer Signature: _____ Date: _____</p> <p>UPC: _____</p> <p>Item #: _____</p> <p>NDC: _____</p> <p>Artist: _____</p>	<p>PFI Code: 1212-22453F-S020</p> <p>Name: Ibuprofen Cold & Sinus Caps x 20</p> <p>Part#: BX3836F GF ER U</p> <p>Dimensions: 2-7/16" x 13/16" x 4-7/16"</p> <p>Proof Size: 100%</p> <p>ITS: 1212453206</p>	<p>Colors:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>PMS 1805</td> <td></td> <td>Black</td> </tr> <tr> <td>PMS</td> <td>PMS</td> <td></td> </tr> <tr> <td>PMS</td> <td>PMS</td> <td>DIE LINE</td> </tr> </table>	PMS 1805		Black	PMS	PMS		PMS	PMS	DIE LINE
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