

<p>PEEL BACK HERE</p>	<p>KEEP CARTON OPEN KEEP WARNINGS INFORMATION</p>	<p>200 mg (Provided as Ibuprofen Sodium 256 mg) Pain Reliever/Fever Reducer (NSAID)</p> <p>10 TABLETS</p>	<p>Distributed By Perrigo Allegan, MI 49010</p>	<p>CODE AREA <i>• no varnish • no color</i></p> <p>: 85852 FA F1</p>
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TOP PLY
TOP PLY - UP TO 7 COLORS ONLY

<p>a serious condition, age 60 or over, taking any other drug or have stomach problems. ■ This product may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away. Do not use this product if you have ever had an allergic reaction to any other pain reliever/fever reducer. ■ Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing aspirin ■ take other nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed. ■ The risk of heart attack or stroke may increase if you use more than directed or for longer than directed. ■ Do not take more than directed. ■ Do not take more than directed. ■ The smallest effective dose should be used. ■ Adults and children 12 years and over: 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, unless directed by a doctor. ■ Children under 12 years: ask a doctor each tablet contains: sodium 23 mg. Contains FD&C yellow #6 aluminum lake. <i>Questions or comments?</i> 1-800-719-9240</p>	<p>ADHESIVE AREA NO COPY</p>
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BASE PLY (2-PLY)
BASE PLY - ONE COLOR ONLY
SAME COLOR AS BACK COPY

ACTUAL SIZE

FA85852F1 ELE 689

<p>PEEL BACK HERE</p>	<p>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</p> <p>Uses ■ temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis. ■ temporarily reduces fever</p> <p>Warnings ■ Ask your doctor before use if you are pregnant, under a doctor's care for</p>	<p style="text-align: center;">Perrigo®</p> <p style="text-align: center;">Ibuprofen Tablets 200 mg (Provided as Ibuprofen Sodium 256 mg) Pain Reliever/Fever Reducer (NSAID)</p> <p style="text-align: center;">10 TABLETS</p>	<p>DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING</p> <p>CODE AREA <i>• no varnish • no color</i></p> <p>: 85852 FA F1</p>	<p>Distributed By Perrigo Allegan, MI 49010</p>
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TOP PLY
TOP PLY - UP TO 7 COLORS ONLY

<p>a serious condition, age 60 or over, taking any other drug or have stomach problems. ■ This product may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away. Do not use this product if you have ever had an allergic reaction to any other pain reliever/fever reducer. ■ Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing aspirin ■ take other nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed. ■ The risk of heart attack or stroke may increase if you use more than directed or for longer than directed. ■ Do not take more than directed. ■ Do not take more than directed. ■ The smallest effective dose should be used. ■ Adults and children 12 years and over: 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, unless directed by a doctor. ■ Children under 12 years: ask a doctor each tablet contains: sodium 23 mg. Contains FD&C yellow #6 aluminum lake. <i>Questions or comments?</i> 1-800-719-9240</p>	<p>ADHESIVE AREA NO COPY</p>
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BASE PLY (2-PLY)
BASE PLY - ONE COLOR ONLY
SAME COLOR AS BACK COPY

150% FOR REVIEW ONLY

Draft Labeling
 ANDA 206581
 Ibuprofen Sodium Caplets, 256 mg
 80 Count Label

FA85827F1 ELA 25H

Perrigo®

**Ibuprofen
 Tablets
 200 mg**
 (Provided as Ibuprofen
 Sodium 256 mg)
 Pain Reliever/Fever Reducer (NSAID)

80 TABLETS

**DO NOT USE IF PRINTED SEAL UNDER CAP
 IS BROKEN OR MISSING**

**READ AND KEEP CARTON FOR COMPLETE
 WARNINGS AND INFORMATION**

Uses ■ temporarily relieves minor aches and pains due to: headache, muscle aches, menstrual cramps, the common cold, toothache, toothache, minor pain of arthritis. ■ temporarily reduces fever

Warnings ■ Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems. ■ This product may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away. Do not use this product if you have ever had an allergic reaction to any other pain reliever/fever reducer. ■ **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or any other problems with your stomach ■ take aspirin, aspirin or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed. ■ The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Directions ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: 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 ■ children under 12 years: ask a doctor ■ each tablet contains sodium 23 mg

Contains FD&C yellow #6 aluminum lake
 Questions or comments? 1-800-719-9240

Distributed By Perrigo
 Allegan, MI 49010

**CODE
 AREA**
 • no varnish • no color
 : 85827 FA F1

ACTUAL SIZE

FA85827F1 ELA 25H

Perrigo®

**Ibuprofen
 Tablets
 200 mg**
 (Provided as Ibuprofen
 Sodium 256 mg)
 Pain Reliever/Fever Reducer (NSAID)

80 TABLETS

**DO NOT USE IF PRINTED SEAL UNDER CAP
 IS BROKEN OR MISSING**

**READ AND KEEP CARTON FOR COMPLETE
 WARNINGS AND INFORMATION**

Uses ■ temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis. ■ temporarily reduces fever

Warnings ■ Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems. ■ This product may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away. Do not use this product if you have ever had an allergic reaction to any other pain reliever/fever reducer. ■ **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed. ■ The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Directions ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: 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 ■ children under 12 years: ask a doctor ■ each tablet contains sodium 23 mg

Contains FD&C yellow #6 aluminum lake
 Questions or comments? 1-800-719-9240

Distributed By Perrigo
 Allegan, MI 49010

**CODE
 AREA**
 • no varnish • no color
 : 85827 FA F1

140% FOR REVIEW ONLY

NON-DFL FORMAT

TYPE SIZES:

HEADINGS: 5 pt Helvetica Neue 77 Bold Cond Oblique

SUBHEADINGS: 5 pt Helvetica Neue 77 Bold Cond

TEXT: 5 pt Helvetica Neue 57 Cond

LEADING: 5.5 pt

BULLETS: 4 pt Square with 3 spaces between statements

TELEPHONE #: 5 pt Helvetica Neue 77 Bold Cond

LINES: 0.75 pt

Draft Labeling
 ANDA 206581
 Ibuprofen Sodium Caplets, 256 mg
 1000 Count Label

FA8593F1 ELA 34A

Perrigo®

**Ibuprofen
 Tablets 200 mg**
 (Provided as
Ibuprofen Sodium 256 mg)
 Pain Reliever/Fever Reducer (NSAID)

FILM-COATED
 IBUPROFEN
 SODIUM
 Caplets**

1000 TABLETS
 **capsule shaped tablets

Drug Facts
Active ingredient (in each tablet)
 Ibuprofen 200 mg (provided as ibuprofen sodium 256 mg) (NSAID).....Pain reliever/fever reducer
 Ibuprofen sodium 256 mg (NSAID).....Pain reliever/fever reducer
 Do not use if printed seal under cap is broken or missing

Uses
 Temporarily relieves minor aches and pains due to:
 ■ headache ■ toothache ■ backache ■ menstrual cramps
 ■ the common cold ■ muscle aches ■ minor pain of arthritis
 Temporarily reduces fever

Warnings
 Always alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.
 Symptoms may include:
 ■ hives ■ facial swelling ■ asthma (wheezing) ■ stomach pain ■ skin redness ■ rash ■ hives
 If an allergic reaction occurs, stop use and seek medical help right away.
 Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding.
 The chance is higher if you:
 ■ are age 60 or older ■ have had stomach ulcers or bleeding problems
 ■ take a blood thinning (anticoagulant) or steroid drug
 ■ take other drugs containing aspirin, naproxen, or other NSAIDs (aspirin, ibuprofen, naproxen, or others)
 ■ have 3 or more alcoholic drinks every day while using this product
 ■ take more or for a longer time than directed
 Do not use ■ If you have ever had an allergic reaction to any other pain reliever/fever reducer
 ■ if you are taking aspirin ■ stomach bleeding warning applies to you
 ■ if you have a history of stomach problems, such as heartburn
 ■ if you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
 ■ if you are taking diuretics
 Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious condition
 ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease its benefit for aspirin
 ■ taking any other drug
 When using this product ■ take with food or milk if stomach upset occurs
 ■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed
 Stop use and ask a doctor if
 ■ you experience one of the following signs of stomach bleeding:
 ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better
 ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present in the painful area ■ any new symptoms appear
 If pregnant or breast-feeding, ask a health professional before use. It is especially important to use
 ibuprofen 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. (1-800-222-1222)

Directions
 ■ do not take more than directed ■ the smallest effective dose should be used
 ■ adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
 ■ 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
 ■ children under 12 years: ask a doctor
Other information
 ■ each tablet contains sodium 23 mg ■ read all warnings and directions before use
 ■ store at 20°-25°C (68°-77°F) ■ avoid excessive heat above 40°C (104°F)

Inactive ingredients color lake silicon dioxide, iron oxide yellow, iron oxide black, polyethylene glycol, polyvinyl alcohol, sodium lauryl sulfate, talc, titanium dioxide

Questions or comments? 1-800-719-9240
 Distributed By
 Perrigo®
 Allegheny, MI 49010
 CODE AREA
 • no tampering • no color
 : 8593 FA F1



TO ARTIST:
 DO NOT use color
 behind the Part #.
 DO NOT change
 position of part #.

STANDARD FORMAT
TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Cond Oblique
 HEADINGS: 8 pt Helvetica Neue 77 Bold Cond Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond
 TEXT: 6 pt Helvetica Neue 57 Cond
 LEADING: 6.5 pt
 BULLETS: 5 pt Square with 2 M's spacing between statements
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

Draft Labeling
 ANDA 206581
 Ibuprofen Sodium Caplets, 256 mg
 10 Count Carton



Perrigo®

Ibuprofen Tablets 200 mg

(Provided as Ibuprofen Sodium 256 mg)

Pain Reliever/Fever Reducer (NSAID)

10 TABLETS
**capsule shaped tablets

FILM-COATED
 IBUPROFEN
 SODIUM
Caplets**





READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active Ingredient (in each tablet) Purpose
 Ibuprofen 200 mg (provided as
 Ibuprofen sodium 256 mg) (NSAID)* Pain reliever/
 *nonsteroidal anti-inflammatory drug Fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - backache
 - the common cold
 - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- facial swelling
- asthma (wheezing)
- skin redness
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take alcohol (drinking, medicinal) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed



DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 3 days
- fever, redness or swelling is present in the painful area
- any new symptoms appear

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.



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LOT NO. CODE AREA

EXP.

: 85852 FA C1

MODIFIED FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Cond Oblique

TITLE (continued): 7 pt Helvetica Neue 77 Bold Cond Oblique

(continued) 7 pt Helvetica Neue 57 Cond

HEADINGS: 7 pt Helvetica Neue 77 Bold Cond Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Cond

TEXT: 6 pt Helvetica Neue 57 Cond

LEADING: 6 pt

BULLETS: 5 pt Square with 2 M'S spacing between statements

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Cond

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

Draft Labeling
 ANDA 206581
 Ibuprofen Sodium Caplets, 256 mg
 80 Count Carton



Perrigo®

Ibuprofen Tablets 200 mg

(Provided as Ibuprofen Sodium 256 mg)

Pain Reliever/Fever Reducer (NSAID)

80 TABLETS
**capsule shaped tablets

FILM-COATED
 IBUPROFEN
 SODIUM
Caplets**





READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active Ingredient (in each tablet) Purpose
 Ibuprofen 200 mg (provided as
 Ibuprofen sodium 256 mg) (NSAID)*Pain reliever/
 *nonsteroidal anti-inflammatory drugFever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - backache
 - the common cold
 - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- facial swelling
- asthma (wheezing)
- skin redness
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take alcohol (drinking/anticipating) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed



DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 3 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the genital area
- any new symptoms appear

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.



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LOT NO. CODE AREA

EXP.

: 85827 FA C1



Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: 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
- children under 12 years: ask a doctor

Other information

- each tablet contains sodium 23 mg
- read all warnings and directions before use.
- keep carton.
- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40° C (104°F)

Inactive ingredients colloidal silicon dioxide, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, glyceryl monostearate, iron oxide yellow, mannitol, polyethylene glycol, polyvinyl alcohol, sodium lauryl sulfate, talc, titanium dioxide

Questions or comments? 1-800-770-9240

Distributed By
Perrigo®
 Allegan, MI 49010



MODIFIED FORMAT

TYPE SIZES:

TITLE: 8 pt Helvetica Neue 77 Bold Cond Oblique
 TITLE (continued): 7 pt Helvetica Neue 77 Bold Cond Oblique
 (continued) 7 pt Helvetica Neue 57 Cond
 HEADINGS: 7 pt Helvetica Neue 77 Bold Cond Oblique
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 HAIRLINES: 0.5 pt