

If taken use if you are a doctor's care for ASK HERE	It relieves minor aches and pains, the menstrual cramps, the headache, the flu, the common cold, the toothache, the minor pain of arthritis, temporarily reduces fever. ■ Warnings: ■ Ask your doctor before use if you are pregnant, under a doctor's care for	200 mg (Provided as Ibuprofen Sodium 256 mg) Pain Reliever/Fever Reducer (NSAID) 10 TABLETS	Distributed By Perrigo Allegan, MI 49010	CODE AREA • no varnish • no color : 85852 FA F1
	■ 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			

TOP PLY
TOP PLY - UP TO 7 COLORS ONLY

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 allergic reaction (such as hives and rash), 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.	ADHESIVE AREA NO COPY
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BASE PLY (2-PLY)
BASE PLY - ONE COLOR ONLY
SAME COLOR AS BACK COPY

ACTUAL SIZE

FA85852F1 ELE 689

PEEL BACK HERE	■ 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	Perrigo® Ibuprofen Tablets 200 mg (Provided as Ibuprofen Sodium 256 mg) Pain Reliever/Fever Reducer (NSAID) 10 TABLETS	Distributed By Perrigo Allegan, MI 49010	DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING CODE AREA • no varnish • no color : 85852 FA F1
	■ Warnings: ■ Ask your doctor before use if you are pregnant, under a doctor's care for			

TOP PLY
TOP PLY - UP TO 7 COLORS ONLY

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.	ADHESIVE AREA NO COPY
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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

<p>Perrigo®</p> <p>Ibuprofen Tablets 200 mg (Provided as Ibuprofen Sodium 256 mg) Pain Reliever/Fever Reducer (NSAID)</p> <p>80 TABLETS</p>	<p>DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING</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</p> <p>■ 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.</p> <p>■ 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.</p> <p>Directions</p> <p>■ do not take more than directed</p> <p>■ the smallest effective dose should be used</p> <p>■ adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist</p> <p>■ if pain or fever does not respond to 1 tablet, 2 tablets may be used</p> <p>■ do not exceed 6 tablets in 24 hours, unless directed by a doctor</p> <p>■ children under 12 years: ask a doctor</p> <p>■ each tablet contains: sodium 23 mg</p> <p>Contains FD&C yellow #6 aluminum lake</p> <p>Questions or comments? 1-800-719-5240</p> <p>Distributed By Perrigo Allergan, MI 49010</p>	<p>CODE AREA • no varnish • no color</p> <p>85827 FA F1</p>
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ACTUAL SIZE

FA85827F1 ELA 25H

<p>Perrigo®</p> <p>Ibuprofen Tablets 200 mg (Provided as Ibuprofen Sodium 256 mg) Pain Reliever/Fever Reducer (NSAID)</p> <p>80 TABLETS</p>	<p>DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING</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</p> <p>■ 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.</p> <p>■ 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.</p> <p>Directions</p> <p>■ do not take more than directed</p> <p>■ the smallest effective dose should be used</p> <p>■ adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist</p> <p>■ if pain or fever does not respond to 1 tablet, 2 tablets may be used</p> <p>■ do not exceed 6 tablets in 24 hours, unless directed by a doctor</p> <p>■ children under 12 years: ask a doctor</p> <p>■ each tablet contains: sodium 23 mg</p> <p>Contains FD&C yellow #6 aluminum lake</p> <p>Questions or comments? 1-800-719-5240</p> <p>Distributed By Perrigo Allergan, MI 49010</p>	<p>CODE AREA • no varnish • no color</p> <p>85827 FA F1</p>
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140% FOR REVIEW ONLY

NON-DLF 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

FA85893F1 ELA 34A



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Peritigo
Algon, MI 49010

CODE AREA
NO REMOVAL OF THIS COLOR
: 85893 FA F1

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

Perrigo®

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

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

Uses
temporarily relieves minor aches and pains due to:
headache
toothache
backache
muscle aches
rheumatism
temporarily reduces fever

Warnings
Allergenic: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.
Symptoms may include:
hives
facial swelling
asthma (wheezing)
stomach
skin rash
blisters
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 or naproxen, or others
have 3 or more blood thinners 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
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 aspirin
you are taking aspirin, salicylate, or other aspirin or aspirin-like products
Ask a doctor or pharmacist before use if you are:
under a doctor's care for any condition
taking aspirin to treat a headache or for any other condition
When using this product:
take with food or milk if stomach upset occurs
the risk of a stroke 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 or symptoms that do not get better:
fever
vomiting
black stools
have stomach pain that does not get better
feel faint
you expect a change in the following signs or symptoms:
redness or swelling 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 up to ten during the last 3 months of pregnancy unless directed to do so by a doctor because it may cause problems in the newborn 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
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
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 #5 aluminum lake, glyceryl monostearate, 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
Peritigo
Algon, MI 49010

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

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



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**

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Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact 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? 1-800-719-9240

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 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 this 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 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. Ibuprofen may harm an unborn child or a nursing infant. It is especially important to avoid ibuprofen during the last 6 weeks of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Active ingredient (in each tablet): Ibuprofen 200 mg (provided as Ibuprofen sodium 256 mg) (NSAID) *...Fever reducer/nonsteroidal anti-inflammatory drug

Purpose: Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - toothache
 - menstrual cramps
 - 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
- hives (itching)
- skin redness
- rash
- dizziness

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 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

Distributed By

Perrigo®
Allegan, MI 49010

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 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 this 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 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. Ibuprofen may harm an unborn child or a nursing infant. It is especially important to avoid ibuprofen during the last 6 weeks of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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Allegan, MI 49010

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Perrigo®
Allegan, MI 49010

LOT NO.

EXP.

0 00000 00000 0

CODE AREA

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85852 FA C3

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

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



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**

0000000000



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 this 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 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 ask a health professional during the last 6 weeks of pregnancy unless advised 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.

: 85A27 FA C3



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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

EFB 110

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