

IBUPROFEN- ibuprofen tablet, film coated
Rebel Distributors Corp

Ibuprofen

Active ingredient (in each brown tablet)

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- Temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - backache
 - menstrual cramps
 - the common cold
 - muscular aches
 - 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:

- shock
- hives
- facial swelling
- asthma (wheezing)
- skin reddening
- 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 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 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

- the 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
- redness or swelling is present in the painful area
- fever gets worse or lasts more than 3 days
- any new symptoms occur

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.

Directions

- **do not use more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- 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 take more than 6 tablets in 24 hours unless directed by a doctor

- children under 12 years: ask a doctor

Other information

- store at controlled room temperature
- avoid excessive heat 40°C (104°F)

Inactive ingredients

carnauba wax, cellulose, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

Call 1-800-540-3765

Package label

Peel **Peel** **Peel** **Peel**

PHYSICIAN PARTNER
A DIVISION OF KECEL DISTRIBUTION CORP.

NDC 42254-315-30

**Ibuprofen 200mg
#30 Tablets**

Each tablet contains: Ibuprofen USP, 200mg (NSAID) Pain Reliever / Fever Reducer Nonsteroidal Anti-Inflammatory Drug

Round brownish red tablet biconvex embossed "44 over 291" on one side and plain on the other side.

Lot #: 000000
Exp. 00/00/00

Q1031530

Product ID: Q1031530

Rx# Master
Dist. By: Geri-Care Pharmaceuticals Corp. 1650 63 Street, Brooklyn, New York 11204

Packaged by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

SEE NEW WARNINGS

IBUPROFEN

pain reliever/fever reducer (NSAID)

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL*

100 Tablets

200 mg each

Tamper Evident:

Do not use if imprinted seal under cap is missing or broken.

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-315(NDC:57896-941)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-315-20	20 in 1 BOTTLE		
2	NDC:42254-315-28	28 in 1 BOTTLE		
3	NDC:42254-315-30	30 in 1 BOTTLE		
4	NDC:42254-315-40	40 in 1 BOTTLE		

5	NDC:42254-315-50	50 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075010	01/01/2004		

Labeler - Rebel Distributors Corp (118802834)

Registrant - PSS World Medical, Inc. (101822862)

Establishment

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-315)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-315)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-315) , REPACK(42254-315)

Establishment

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-315) , REPACK(42254-315)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-315)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-315) , REPACK(42254-315)