IBUPROFEN- ibuprofen tablet, film coated
Proficient Rx LP

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Ibuprofen 200mg (OTC)

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:

hives
facial swelling
asthma (wheezing)
shock
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:

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

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

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

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

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
have bloody or black stools
vomit blood
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 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 take more than directed
the smallest effective dose should be used

1. 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

store between 20°-25°C (68°-77°F)
avoid excessive heat 40°C (104°F)
use by expiration date on package

Inactive ingredients

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

Questions or comments?

(800) 616-2471

Principal Display Panel

NDC 63187-598-30

†Compare to the active ingredient in Advil® Tablets

Ibuprofen
Tablets
Ibuprofen Tablets, USP 200 mg

Pain Reliever
Fever Reducer **(NSAID)**

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

50844 REV0112D29116

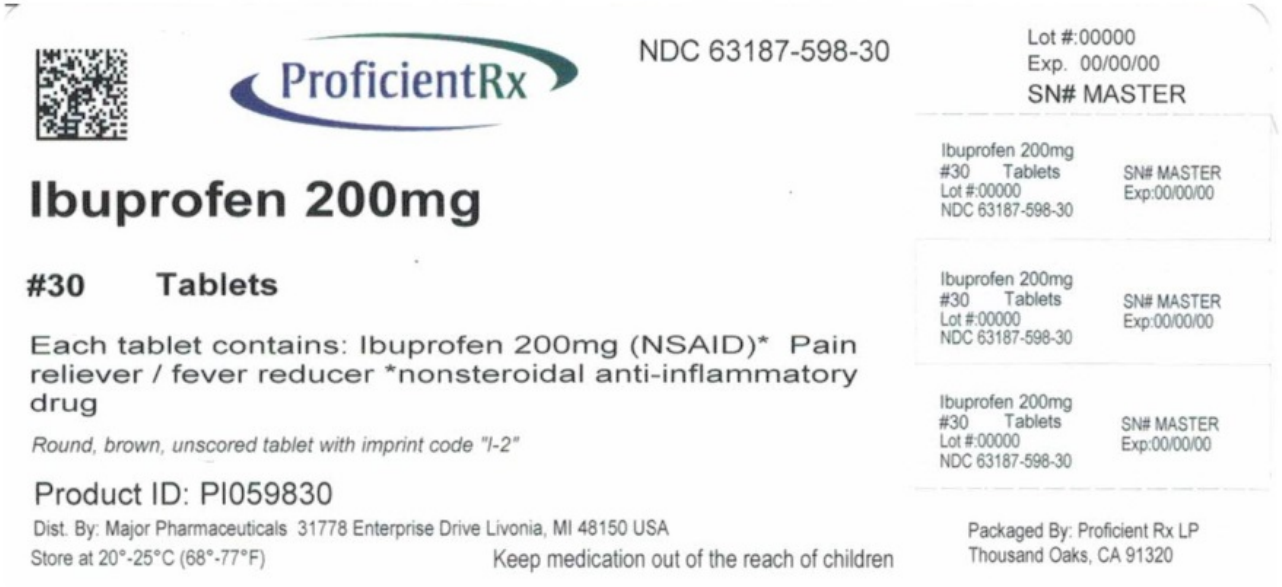
Distributed by
MAJOR PHARMACEUTICALS
31778 Enterprise Drive
Livonia, MI 48150 USA M-17 Rev.01/13

Repackaged by:

Proficient Rx LP

Thousand Oaks, CA 91320

Re-order No. 700643



IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-598(NDC:0904-7915)
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**
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	BROWN	**Score**	no score

Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-598-06	06 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2015	
2	NDC:63187-598-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2018	
3	NDC:63187-598-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2015	
4	NDC:63187-598-40	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2015	
5	NDC:63187-598-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/05/2017	
6	NDC:63187-598-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2015	
7	NDC:63187-598-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/24/1988	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-598) , RELABEL(63187-598)

Revised: 11/2019 Proficient Rx LP