# IBUPROFEN- ibuprofen tablet, film coated CHAIN DRUG MARKETING ASSOCIATION INC

-----

#### Quality Choice 44-292

# Active ingredient (in each brown caplet)

Ibuprofen USP, 200 mg (NSAID)\* \*nonsteroidal anti-inflammatory drug

#### Purpose

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - backache
  - muscular aches
  - toothache
  - menstrual cramps
  - headache
  - 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:

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

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

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

- are age 60 or older
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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 a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you have problems or serious side effects from taking pain relievers or fever reducers

# 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

# 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
- you have symptoms of heart problems or stroke:
  - chest pain
  - slurred speech
  - leg swelling
  - trouble breathing
  - weakness in one part or side of body
- 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 at 20 weeks or later in 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
- adults and children 12 years and over: take 1 caplet every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 caplet, 2 caplets may be used
  - do not exceed 6 caplets 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)
- see end flap for expiration date and lot number

# Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

# **Questions or comments?**

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

# Principal display panel

QC<sub>®</sub> QUALITY CHOICE

NDC 63868-979-10

†Compare to the Active Ingredient in Advil® Caplets

Ibuprofen Ibuprofen Tablets USP, 200 mg

Pain Reliever, Fever Reducer **(NSAID)**  100 Coated Caplets

actual size

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

†This product is not manufactured or distributed by PF Consumer Healthcare 1 LLC, owner of the registered trademark Advil® Caplets. 50844 REV1221C29212

Distributed by CDMA, Inc. 43157 W Nine Mile Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362

SATISFACTION GUARANTEED 100% QC



#### QC 44-292

<b>IBUPROFEN</b> ibuprofen tablet, film coated					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	Source)	NDC:63	868-979
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingree	dient Name		Basis of Stre	ngth	Strength

**IBUPROFEN** 

In	active Ingr	edients					
			Ingr	edient Name			Strength
C /	ARNAUBA WAX	(UNII: R12CB	MOEIZ)				
SI	LICON DIOXIDE	(UNII: ETJ7Z	(6XBU4)				
ST	ARCH, CORN (U	JNII: 08232N	IY3SJ)				
H١	PROMELLOSE,	UNSPECIF	IED (UNII: 3NX)	W29V3WO)			
41	NHYDROUS LAC	TOSE (UNII:	3SY5LH9PMK)				
M	AGNESIUM STE	ARATE (UNII	: 70097M6I30)				
MI	CROCRYSTALL	INE CELLUL	OSE (UNII: OP	1R32D61U)			
PC	DLYDEXTROSE	(UNII: VH2XO	0U12IE)				
				JNII: 3WJQOSDW1A)			
	RRIC OXIDE RE						
				<b>FATO</b> (UNII: 5856J3G	2A2)		
	EARIC ACID (UI						
Гľ		<b>DE</b> (UNII: 15F	IX9V2JP)				
P	roduct Char	actoristi	<b>~</b> 5				
	olor	acteristi	brown	Score		no	score
	nape		OVAL	Size			mm
	avor		OVAL	Imprint Code			;292
	ontains				3		,292
	ontains						
Pa	ackaging						
#	ltem Code		Package I	Description	Marketing Date	Start	Marketing End Date
1	NDC:63868- 979-24	1 in 1 CART	ON		05/24/1988		
1		24 in 1 BOT Combinatio	TTLE, PLASTIC; n Product	Type 0: Not a			
2	NDC:63868- 979-50	1 in 1 CART	ON		05/24/1988		
2		50 in 1 BO Combinatio	TTLE, PLASTIC; n Product	Type 0: Not a			
3	NDC:63868- 979-10	1 in 1 CART	ON		05/24/1988		

100 in 1 BOTTLE, PLASTIC; Type 0: Not a 3 Combination Product

#### **Marketing Information** Marketing End Marketing **Application Number or Monograph Marketing Start** Date Citation Category Date ANDA ANDA075010 05/24/1988

#### Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(63868-979)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(63868-979)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(63868-979)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(63868-979)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(63868-979)

Revised: 4/2024

CHAIN DRUG MARKETING ASSOCIATION INC