

IBUPROFEN- ibuprofen capsule, liquid filled
TARGET CORPORATION

TARGET 610T -IBUPROFEN 200 MG SOFTGELS NDC 11673-992

ACTIVE INGREDIENT(S)

Solubilized ibuprofen equal to 200 mg ibuprofen
(present as the free acid and potassium salt)

INACTIVE INGREDIENTS

Ammonium Hydroxide, FD&C Green No. 3, Gelatin, Iron oxide black, Medium-chain triglycerides, Polyethylene glycol, Propylene glycol, Potassium hydroxide, Purified water, Shellac, Sorbitol sorbitan, Sorbitan monooleate.

PURPOSE

Pain reliever/Fever reducer

*nonsteroidal anti-inflammatory drug

USE(S)

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

DIRECTIONS

do not take more than directed

the smallest effective dose should be used

adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
if pain or fever does not respond to 1 capsule, 2 capsules may be used

do not exceed 6 capsules in 24 hours, unless directed by a doctor

children under 12 years: ask a doctor

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

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 a nonsteroidal anti-inflammatory drug (NSAIDs), 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

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.

NDC 11673-002-44

Ibuprofen

Ibuprofen Capsules, 200 Mg
Pain Reliever /
Fever Reducer (NSAID)

40 SOFTGELS**
(**LIQUID-FILLED CAPSULES)

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS COIL, TORN, BROKEN OR MISSING.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Uses ■ temporarily relieves minor aches and pains due to headache, toothache, muscle aches, menstrual cramps, 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. Stop use if you experience any of the following:

■ stomach pain or heartburn ■ indigestion ■ nausea ■ vomiting ■ diarrhea ■ constipation ■ black or tarry stools ■ blood in stool ■ blood in urine ■ blood in vomit ■ blood in stool ■ blood in urine ■ blood in vomit

■ 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 ■ use grape or topiramate with this product

Caution: NSAIDs, including ibuprofen, may 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 problems or serious side effects with any of the following: ■ heart disease ■ high blood pressure ■ kidney disease ■ asthma, or had a stroke ■ you are taking a diuretic

■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ■ you are taking a diuretic

Directions ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 capsule, 2 capsules may be used

■ children under 12 years: ask a doctor ■ each capsule contains **ibuprofen 200 mg**

Questions? Call 1-800-910-6874

D94-01-0388

Dist. by: Targor Corp., Wpls., WI 55403

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Lot No. _____

Exp. Date: _____

Varnish Omit Area

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-992
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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIA (UNII: 5138Q19F1X)	
FERROUS OXIDE (UNII: G7036X8B5H)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-992-44	40 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	
2	NDC:11673-992-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079205	01/01/2020	

Labeler - TARGET CORPORATION(006961700)

Registrant - TIME CAP LABORATORIES, INC (037005209)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11673-992)

Revised: 5/2020

TARGET CORPORATION