IBUPROFEN- ibuprofen tablet, coated DOLGENCORP INC

601R-DOLLAR GENERAL - IBUPROFEN TABLETS 200 MG 55910-901

Ibuprofen 200 mg (NSAID)*

* nonstreoidal anti-inflammatory drug

Silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.

Pain reliever / fever reducer

USE(S)

temporarily relieves minor aches and pains due to:

backache

headache

menstrual cramps

minor pain of arthritis

muscular aches

the common cold

toothache

temporarily reduces fever

WARNINGS

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

asthma (wheezing)

blisters

facial swelling

hives

rash

shock

skin reddening

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 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: NSAID's except aspirin increases the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or longer than directed.

DIRECTIONS

do not take more than directed

the smallest effective dose should be used

adults and children 12 years and older:

take 1 tablet every 4 to 6 hours while symptoms persist

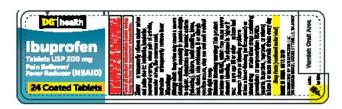
if pain or fever does not respond to 1 tablet, 2 tablets may be used do not exceed 6 tablets in 24 hours, unless directed by a doctor.

Children under 12 years:

ask a doctor

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)



IBUPROFEN			
ibuprofen tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-901
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg	

Inactive Ingredients	
Ingredient Name	Strength
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28 OL 1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	bro wn	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	114	
Contains				

l	Pa	ckaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 N	IDC:55910-901-42	24 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091239	12/09/2019		

Labeler - DOLGENCORP INC (068331990)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	repack(55910-901)

Establishment			
Name	Address	ID/FEI	Business Operations

marksans pharma ltd 925822975 manufacture(55910-901)

Revised: 9/2019 DOLGENCORP INC