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**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC: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)