8 HR PAIN RELIEF- acetaminophen tablet, extended release
DOLGENCORP, INC.

704R 55910-895 Dollar General Acetaminophen Extended-Release Tablets 650 mg - Muscle Aches & Pain

Drug Facts

Active ingredient (in each caplet)
Acetaminophen 650 mg

Purpose
Pain reliever/fever reducer

Uses
• temporarily relieves minor aches and pains due to:
o muscular aches
o backache
o minor pain of arthritis
o toothache
o premenstrual and menstrual cramps
o headache
o the common cold
• temporarily reduces fever

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
• more than 6 caplets in 24 hours, which is the maximum daily amount
• with other drugs containing acetaminophen
• 3 or more alcoholic drinks every day while using this product
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
• skin reddening
• blisters
• rash
If a skin reaction occurs, stop use and seek medical help right away.

Do not use
• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
• if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.
Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
Do not take more than directed.
See overdose warning
adults and children 12 years and over

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split, or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

children under 12 years

- do not use

Other information
- store at 20-25ºC (68-77ºF)
- The FDA approved Dissolution methods differ from USP

Inactive ingredients carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments? Call **1-877-290-4008**

8 HR PAIN RELIEF

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-895
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
TRIACETIN (UNII: XHX3C3X673)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white (White to off White)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-895-05	1 in 1 BOTTLE	04/29/2023	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	04/29/2023	

Labeler - DOLGENCORP, INC. (068331990)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma Ltd		925822975	manufacture(55910-895)

Revised: 4/2023 DOLGENCORP, INC.