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

699R Dollar General 55910-892 Acetaminophen Extended Release Tablets 650 mg Arthritis 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 minor pain of arthritis
- o muscular aches
- o backache
- o premenstrual and menstrual cramps
- o the common cold
- o headache
- o toothache
- 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

- 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 under 18 years of age
- ask a doctor

Other information

- store between 20-25°C (68-77°F)
- 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**



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do not use for more than 10 days unless directed by a doctor

<mark>∪e</mark>"|health

ask a doctor

Pain Relief

hr Arthritis

under 18 years of age

Pain Reliever/Fever Reducer **Acetaminophen** Extended-Release Tablets, 650 mg

or the Temporary Relief of Minor Arthritis Pain

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help right away.

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| DISTRIBUTED BY OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 370721 |
| 699R 0123 Made in India NDC 55910-892-05 • minor pain of arthritis • muscular aches • backache
• premenstrual and menstrual cramps • the common cold
• headache • brothache ■ temporarily reduces fever

Warnings Liver warning: This product contains acetaminophen.
Severe liver damage may occur if you take ■ more than 6 caplers in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen **a** 3 or more alcoholic drinks every day while using this product **Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include: **DG**™|health ■ swallow whole, do not crush, chew, split or dissolve ■ do not take more than 6 caplets in 24 hours ■ do not use for m than 10 days unless directed by a doctor under 18 years of Uses ■ temporarily relieves minor aches and pains due to: warning adults: ■ take 2 caplets every 8 hours with water **Arthritis** Omit Area **BROKEN OR** Acetaminophen Extended-Release Tablets USP, 650 mg IMPRINTED FOIL SEAL BOTTLE IS CUT, TORN, Pain Reliever/Fever Reducer For the Temporary Relief of Minor Arthritis Pain DO NOT USE WITH OTHER MEDICINES **CONTAINING ACETAMINOPHEN** Date: 50 Caplets**-650 mg Each ot No.:

> Exb Date: Varnish Omit Lot No.:

> 22610 86502

TAMPER CHOEFT TO NOT USE THIS PRODUCT IF

THE IMPRINTED CHIL SECL. THAN 100.

THAN

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each caplet)

Purpose

fever reduce

temporarily relieves minor aches and pains

- due to:

 minor pain of arthritis

 muscular aches backache

 premenstrual and menstrual cramps
- the common cold headache
- toothache
- temporarily reduces fever

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 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.

Drug Facts (continued)

(**Capsule Shaped Bi-Layer Tablets)

- 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.
- 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
- davs

Pain Reliever/Fever Reducer lablets USP, 650 mg

Acetaminophen Extended-Release

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hr Arthritis

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Drug Facts (continued)

See overdose warning

adults

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Other information

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Contains No Aspirin

Directions Do not take more than directed

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 do not use for more than

ask a doctor

■ store between 20-25°C (68-77°F)
■ 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

Acetaminophen Extended-Release Tablets USP, 650 mg 8 hr Arthritis Pain Relief Pain Reliever/Fever Reducer

NDC 55910-892-05
Compare to the active ingredient of Tylenol®
8*** Arthritis Pain**

og"|health

50 Caplets" 650 mg Each

For the Temporary Relief of Minor Arthritis Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

(**Capsule Shaped Bi-Layer Tablets

Varnish/Print Omit Area





8 HR ARTHRITIS PAIN RELIEF

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-892
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 650 mg

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

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-892- 42	1 in 1 CARTON	04/29/2023	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55910-892- 05	1 in 1 CARTON	04/29/2023	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55910-892- 26	1 in 1 CARTON	04/29/2023	
3		225 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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(55910-892)

Revised: 4/2023 DOLGENCORP, INC.