EXCINOL ARTHRITIS (ACETAMINOPHEN)- acetaminophen tablet, delayed release
America Medic & Science, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Excinol Arthritis (Acetaminophen) 650 mg

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Drug Facts

Active Ingredient

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- arthritis
- headache
- muscular aches
- temporarily reduces fever
- the common cold
- toothache
- backache
- menstrual cramps

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Do not use

- with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have liver disease

Ask your 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 appear
- 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

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. 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).

- 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 18 years of age ask a doctor.

Other information

- store between 20-25°C (68-77°F)
- **do not use if neck wrap is broken or missing**
- see end panel for lot number and expiration date

Inactive ingredients

- carnauba wax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?

call toll free 1-855-470-6722

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acetaminophen tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49638-103
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	white	**Score**	no score
Shape	capsule	**Size**	8mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49638-103-30	1 in 1 CARTON	01/17/2019	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/17/2019	

Labeler - America Medic & Science, LLC (071065464)

Registrant - America Medic & Science, LLC (071065464)

Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc		037052099	manufacture(49638-103)

Revised: 1/2019 America Medic & Science, LLC