

**EXCINOL EXTRA (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.*

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**Excinol Extra 1000 mg**

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**Drug Facts**

**Active Ingredient**

Acetaminophen 1000 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

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

**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).**

**Adults and children 12 years and over:**

- take 1 caplet every 6 to 8 hours
- Do not take more than 4 caplets of this product in 24 hours.

**Children under 12 years:**

- do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

**Other information**

- store between 20-25°C (68-77°F)
- see end panel for lot number and expiration date

**Inactive ingredients**

- Carnauba wax, hypromellose, polyethylene glycol, propylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

**Questions or comments?**

call toll free 1-855-470-6722

**Excinol Extra 1000 mg**



## EXCINOL EXTRA (ACETAMINOPHEN)

acetaminophen tablet, delayed release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49 638-111
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg

## Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	white	Score	no score
Shape	capsule (CAPLET)	Size	8mm
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-111-30	1 in 1 CARTON	07/06/2020	
1		24 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 mono graph not final	part343	07/06/2020	

**Labeler** - America Medic & Science, LLC (071065464)

**Registrant** - America Medic & Science, LLC (071065464)

## Establishment

Name	Address	ID/FEI	Business Operations
Elvi Pharma LLC		078739246	manufacture(49638-111)

Revised: 9/2020

America Medic & Science, LLC