

EXCINOL EXTRA- 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 Extra 500 mg

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Drug Facts

Active Ingredient

Acetaminophen 500 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 2 caplets every 4 to 6 hours
- Do not take more than 8 caplets of this product in 24 hours.

Children under 12 years:

- do not use this 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 at 25°C (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 500 mg



EXCINOL EXTRA

acetaminophen tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49638-109
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 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:49638-109-30	1 in 1 CARTON	07/06/2020	
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	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(49638-109)

Revised: 9/2020

America Medic & Science, LLC