EXCINOL NIGHT (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 Night (Acetaminophen)
500 mg

Excinol Night (Acetaminophen)
500 mg

Drug Facts

Active Ingredient

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Night time sleep aid

Uses

- temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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 nonprescription).
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

- Liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask your doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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.

Directions

do not take more than directed (see overdose warning).

Adults and children 12 years and over:

- take 2 caplets at bedtime
- do not take more than 2 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)
- **do not use if neck wrap is broken or missing**
- see end panel for lot number and expiration date

Inactive ingredients

Carnauba wax, FD&C blue# 1 al lake, FD&C blue# 2 al lake, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, stearic acid, titanium dioxide, triacetin.

Questions or comments?

call toll free 1-855-470-6722

Excinol Night (Acetaminophen)
500 mg

EXCINOL NIGHT (ACETAMINOPHEN)

acetaminophen tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49638-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	blue	**Score**	no score
Shape	capsule	**Size**	8mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-105-30	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(49638-105)

Revised: 1/2019 America Medic & Science, LLC