# MIGRENOL- acetaminophen, caffeine tablet Four Ventures Enterprises, Inc.

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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#### **Drug facts**

Active ingredients (in each tablet): Acetaminophen -500 mg, (Pain reliever),

Caffeine -65 mg (Pain reliever aid).

temporary relief of occasional headaches and minor aches and pains due to

headache, muscular aches,

toothache, premenstrual and menstrual cramps

#### DO NOT USE:

- with any other product containing acetaminophen
- if you ever had an allergic reaction to any other pain reliever/fever reducer.

ASK DOCTOR BEFORE USE if you have liver desease.

ASK A DOCTOR OR PHARMACIST BEFORE USE if you are taking sedatives or tranquilizers when using this product

- drowsiness will occur
- avoid alcoholic drinks

#### STOP USE AND ASK A DOCTOR IF

- an allergic reaction occurs. Seek medical help right away.
- -new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.

LIVER WARNING: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 8 tables in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.
- do not take more than directed

Adults and children 12 years and over:

- take 2 tablets every 6 hours
- do not take more than 8 tablets 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

and may cause liver damage.

IF PREGNANT OR BREAST-FEEDING, ask a health professional before use.

Keep out of reach of children.

INACTIVE INGREDIENTS: Croscarmellose Sodium, Dicalcium,

Phosphate, Hypromellose, Microcrystalline Cellulose, Polydextrose, Polyethylene glycol, Povidone, Silica,

Sodium Starch Glycolate, Starch, Stearic Acid.

Pupose: Pain reliever, Fever Reducer



### **MIGRENOL**

acetaminophen, caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69293-565
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg		
CAFFEINE (UNII: 3G6 A5W338 E) (CAFFEINE - UNII:3G6 A5W338 E)	CAFFEINE	6 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
<b>DIBASIC CALCIUM PHO SPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)		
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
STARCH, CORN (UNII: O8232NY3SJ)		

Product Characteristics			
Color	white (snow white)	Score	no score
Shape	ROUND (NONE)	Size	19 mm
Flavor		Imprint Code	NONE
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:69293-565-16	16 in 1 BOX; Type 0: Not a Combination Product	11/10/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/10/2014	

## Labeler - Four Ventures Enterprises, Inc. (944548866)

### **Registrant** - Four Ventures Enterprises, Inc. (944548866)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>

ULTRAtab Laboratories, Inc. 151051757 manufacture(69293-565)

Revised: 11/2018 Four Ventures Enterprises, Inc.