

VICA-CET- acetaminophen, caffeine, magnesium salicylate tablet
Provision Medical Products

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.

Uses:

for temporary relief of mild to moderate pain

associated with BACKACHE, headache, colds, toothache, minor arthritis pain, muscular aches, menstrual cramps

If pregnant or breast-feeding, ask a

health professional before use. IT IS

ESPECIALLY IMPORTANT NOT TO USE

DURING THE LAST 3 MONTHS

OF PREGNANCY UNLESS SPECIFICALLY

DIRECTED TO DO SO BY A DOCTOR,

BECAUSE IT MAY CAUSE PROBLEMS IN

THE UNBORN CHILD OR

COMPLICATIONS DURING DELIVERY.

KEEP OUT OF REACH OF CHILDREN. In

case of overdose, get medical help or

contact a Poison Control Center right

away. Prompt medical attention is

critical for adults as well as for children

even if you do not notice any signs or

symptoms.

Warnings:

Reye's syndrome: Children and teenagers should not

use this medicine for chicken pox or flu symptoms

before a doctor is consulted about Reye's syndrome, a

rare but serious illness reported to be associated with

aspirin.

Allergy Alert: Do not take this product if after

taking a pain reliever or fever reducer you ever had • hives • facial swelling • asthma • shock

Alcohol Warning: If you consume 3 or more

alcoholic drinks every day, ask your doctor whether you

should take acetaminophen and aspirin or other pain

relievers/fever reducers. Acetaminophen and aspirin may

cause liver damage and stomach bleeding.

Ask a doctor before use if you have: • the worst headache of your life • ulcers

- fever and sti neck • asthma
- bleeding problems • liver disease
- renal disease

When using this product:

- limit the use of caffeine containing medications, foods, or beverages while taking this product because too much caFFeine may cause nervousness, sleeplessness, irritability and, occasionally, rapid heart beat.

Stop use and ask a doctor if:

- headache pain worsens or continues for more than 48 hours
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occur

Directions:

Adults and children 12 years of age, no to exceed 8 tablets in 24 hours, or as directed by a doctor.

Children under 12 years: Do not give to children under 12 unless directed by a doctor.

Inactive Ingredients:

hydroxypropyl methylcellulose, maltodextrin,microcrystalline cellulose,polyethylene glycol povidone, sodium starch glycolate, starch, and stearic acid

USP.

ACTIVE INGREDIENT-ACETAMINOPHEN 250 MG, MAGNESIUM SALICYLAYE 250 MG,CAFFEINE 50 mg

PAIN RELIEVER, FEVER REDUCER WITH ADJUVANT



VICA-CET

acetaminophen, caffeine, magnesium salicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 103-2550
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SALICYLATE (UNII: 41728CY7UX) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MAGNESIUM SALICYLATE	250 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg

Inactive Ingredients

Ingredient Name	Strength
CAFFEINE (UNII: 3G6A5W338E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white (SNOW WHITE)	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR32
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69 103-2550-6	100 in 1 CARTON	04/03/2015	
1		2 in 1 PACKET; 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	04/03/2015	

Labeler - Provision Medical Products (036936831)**Registrant** - Provision Medical Products (036936831)**Establishment**

Name	Address	ID/FEI	Business Operations
Ultraseal Corporation		085752004	pack(69 103-2550)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(69 103-2550)

Revised: 4/2015

Provision Medical Products