

PAIN TERMINATOR 2 SEVERE- aspirin, acetaminophen, caffeine 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 headache.

If pregnant or breast-feeding, ask a health professional before use. IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN 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:

cellulose, pharmaceutical glaze,
povidone, starch, stearic acid and talc

USP.

ACTIVE INGREDIENT-ACETAMINOPHEN 250 MG, ASPIRIN 250 MG,CAFFEINE 65 mg
PAIN RELIEVER, FEVER REDUCER WITH ADJUVANT



PAIN TERMINATOR 2 SEVERE

aspirin, acetaminophen, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 103-2533
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg

Inactive Ingredients

Ingredient Name	Strength
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CAFFEINE (UNII: 3G6A5W338E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	white (SNOW WHITE)	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	FR9
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69 103-2533-5	250 in 1 CARTON	04/03/2015	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69 103-2533-6	100 in 1 CARTON	04/03/2015	
2		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(69 103-2533)

Establishment			
Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(69 103-2533)