PAIN FREE PLUS- acetaminophen, aspirin, caffeine tablet Afassco 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.

Drug Facts

Acetaminophen 250mg, Aspirin 250mg, Caffeine 65mg

Pin reliever, Stimulant

Uses: For the temporary relief of pain from:

- headaches muscular aches
- menstrual cramps toothaches
- minor arthritic pain colds

WARNING:

Reye's Syndrome Warning: 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.

Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take: more than 8 tablets in 24 hours

• with other drugs containing acetaminophen (prescription or non-prescription)

• 3 or more alcoholic drinks every day while using this product.

Stomach Bleeding Warning: This product contains nonsteroidal antiinflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you: have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug

• are age 60 or older • have 3 or more alcoholic drinks every day while using this product • take with other drugs containing an NSAID • take more or for a longer time than directed.

Keep out of reach of children.

DIRECTIONS:

Adults: 2 tablets with a full glass of water every 6 hours as needed. Do not exceed 8 tablets in a 24 hour period.

Children under 12 years of age: Consult a doctor.

SEE ORIGINAL BOX FOR COMPLETE PRODUCT INFORMATION



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acetaminophen, aspirin, caffein						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:51532		NDC:51532-0	-0560	
Route of Administration	ORAL					
Active Ingredient/Active M	Ioiety					
Active Ingredient/Active N	Ioiety Ingredient Name		Basis of S	Strength	Strength	
	Ingredient Name	362O9ITL9D)	Basis of S	-	Strength 250	
ACETAMINOPHEN (UNII: 3620911	Ingredient Name FL9D) (ACETAMINOPHEN - UNII::	362O9ITL9D)		-	-	
Active Ingredient/Active M ACETAMINOPHEN (UNII: 362091T ASPIRIN (UNII: R16C05Y76E) (ASE CAFFEINE (UNII: 3G6A5W338E) (C	Ingredient Name FL9D) (ACETAMINOPHEN - UNII: PIRIN - UNII:R16CO5Y76E)	362O9ITL9D)	ACETAMINO	-		
ACETAMINO PHEN (UNII: 362091T ASPIRIN (UNII: R16C05Y76E) (ASF	Ingredient Name FL9D) (ACETAMINOPHEN - UNII: PIRIN - UNII:R16CO5Y76E)	362O9ITL9D)	ACETAMINO ASPIRIN	-	250 250	

POVIDONE (UNII: FZ9)	39GH94E)					
•	,	DRN (UNII: AG9B65PV6B)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) STEARIC ACID (UNII: 4ELV7Z65AP)						
STARCH, CORN (UNII:	,					
HYPROMELLOSES (U	,					
MALTO DEXTRIN (UN						
POLYETHYLENE GLY	,	(UNII: 3WJQ0SDW1A)				
TITANIUM DIO XIDE (,				
Product Characte	ristics					
Color	white	Score		n	io score	
Shape	ROUND	ROUND Size 11mm				
Flavor		Imprint Code		F	7R9	
Contains						
Packaging						
# Item Code	Packa	ge Description	Ma	rketing Start Date	Marketing End Date	
1 NDC:51532-0560-2	2 in 1 PACKET; Type 0): Not a Combination Product	10/25	5/2016		
Marketing Info	rmation					
Marketing Categor		umber or Monograph Citati	on N	Iarketing Start Date	Marketing End Date	
		in our of history gruph chut		-	Line ung Lind Dutt	
OTC monograph not fin	al part343		10	/25/2016		

Labeler - Afassco Inc. (609982723)

Registrant - ULTRAtab Laboratories, Inc. (151051757)

Establishment					
Name	Address	ID/FEI	Business Operations		
ULTRAtab Laboratories, Inc.		151051757	manufacture(51532-0560)		

Establishment	
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Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	pack(51532-0560)

Revised: 9/2019

Afassco Inc.