# PAIN AID ESF - acetaminophen, aspirin and caffeine tablet Zee Medical 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 Ingredient (in each tablet) Acetaminophen 250 mg, Aspirin 250 mg, Caffeine 65 mg

Purpose-Pain reliever, Fever Reducer

#### Uses

- temporarily relieves pain due to:
- headache muscular aches colds flu
- temporarily reduces fever

#### Directions

- adults: take 2 tablets every 6 hours, not more than 8 tablets in 24 hours
- children under 12 years: ask a doctor

#### Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives facial swelling asthma (wheezing) shock Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 8 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat. Do not use

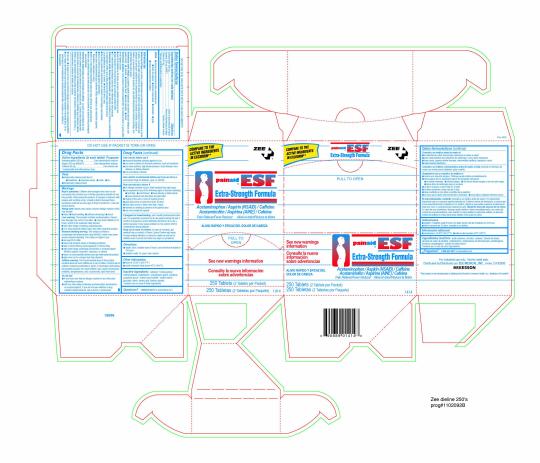
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Stop use and ask a doctor if
- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
- feel faint vomit blood have bloody or black stools
- have stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appearAsk a doctor before use if you are taking a prescription drug for diabetes, gout, or arthritis■ stomach bleeding warning applies to you■ you have a history of stomach problems, such as heartburn you have asthma, high blood pressure, heart disease, live rdisease, or kidney disease■ you are taking a diuretic

If pregnant or breast-feeding baby, ask a health professional before use

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.

Inactive ingredients cellulose\*, hydroxypropyl methylcellulose, maltodextrin\*, polyethylene glycol, povidone, propylene glycol\*, sodium lauryl sulfate\*, sodium starch glycolate, starch, stearic acid, titanium dioxide \*contains one or more of these ingredients

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### **PAIN AID ESF**

acetaminophen, aspirin, caffeine tablet

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:35418-560
Route of Administration	ORAL	DEA Sche dule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	250 mg		
ASPIRIN (ASPIRIN)	ASPIRIN	250 mg		
CAFFEINE (CAFFEINE)	CAFFEINE	65 mg		

Inactive Ingredients	
Ingredient Name	Strength
CELLULO SE, MICRO CRYSTALLINE	
STARCH, CORN	
MALTO DEXTRIN	
POLYETHYLENE GLYCOL 300	
POVIDONE K29/32	

SODIUM LAURYL SULFATE	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STEARIC ACID	
TITANIUM DIO XIDE	

Product Characteristics				
Color	white (snow white)	Score	no score	
Shape	ROUND (ZEE;ESF)	Size	12mm	
Flavor		Imprint Code	ZEE;ESF	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:35418-560-68	50 in 1 CARTON			
1	NDC:35418-560-67	125 in 1 CARTON			
1	NDC:35418-560-70	12 in 1 CARTON			
1	NDC:35418-560-02	2 in 1 PACKET			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	06/12/2012		

## Labeler - Zee Medical Inc (009645623)

### Registrant - Ultra Seal Corporation (085752004)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Ultratab Laboratories, Inc.		151051757	manufacture(35418-560)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ultra Seal Corporation		085752004	repack(35418-560)	

Revised: 11/2012 Zee Medical Inc