

PAIN RELIEVER- acetaminophen, aspirin, caffeine, salicylamide tablet
ADVANCED FIRST AID, 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.

ACTIVE INGREDIENT IN EACH TABLET- ACETAMINOPHEN 110 MG, ASPIRIN 162 MG,
CAFFEINE 32.4 MG, SALICYLAMIDE 152 MG

PAIN RELIEVER/FEVER REDUCER

Uses:

temporarily relieves minor aches and pains associated with:

- headaches • colds • toothache • minor arthritis pain • muscular aches • menstrual cramps • backache

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 behaviour 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: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash. If a skin reaction occurs, stop use and seek medical help right away.

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 an 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 with 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:

- with any other product containing acetaminophen (prescription or nonprescription). This will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns.
- with any other pain reliever/fever reducer
- if you are allergic to aspirin
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor

Ask doctor before using if you have:

- stomach problems (such as heartburn, upset stomach or stomach pain)
- stomach bleeding warning applies to you
- gastric ulcers • bleeding problems
- you have asthma, high blood pressure, heart disease, liver disease, or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are taking a prescription drug for:

- anticoagulation (thinning of blood) • diabetes • gout • arthritis
- under a doctor's care for any serious condition
- taking any other drug

When using this product do not exceed recommended dose.**Stop use and ask a doctor if:**

- ringing in the ears or loss of hearing occurs
- pain or fever persists or gets worse
- new symptoms occur
- redness or swelling is present
- you feel faint, vomit blood or have bloody or black stools, have stomach pain that does not get better. These are signs of stomach bleeding.
- an allergic reaction occurs.

Seek medical help right away.

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

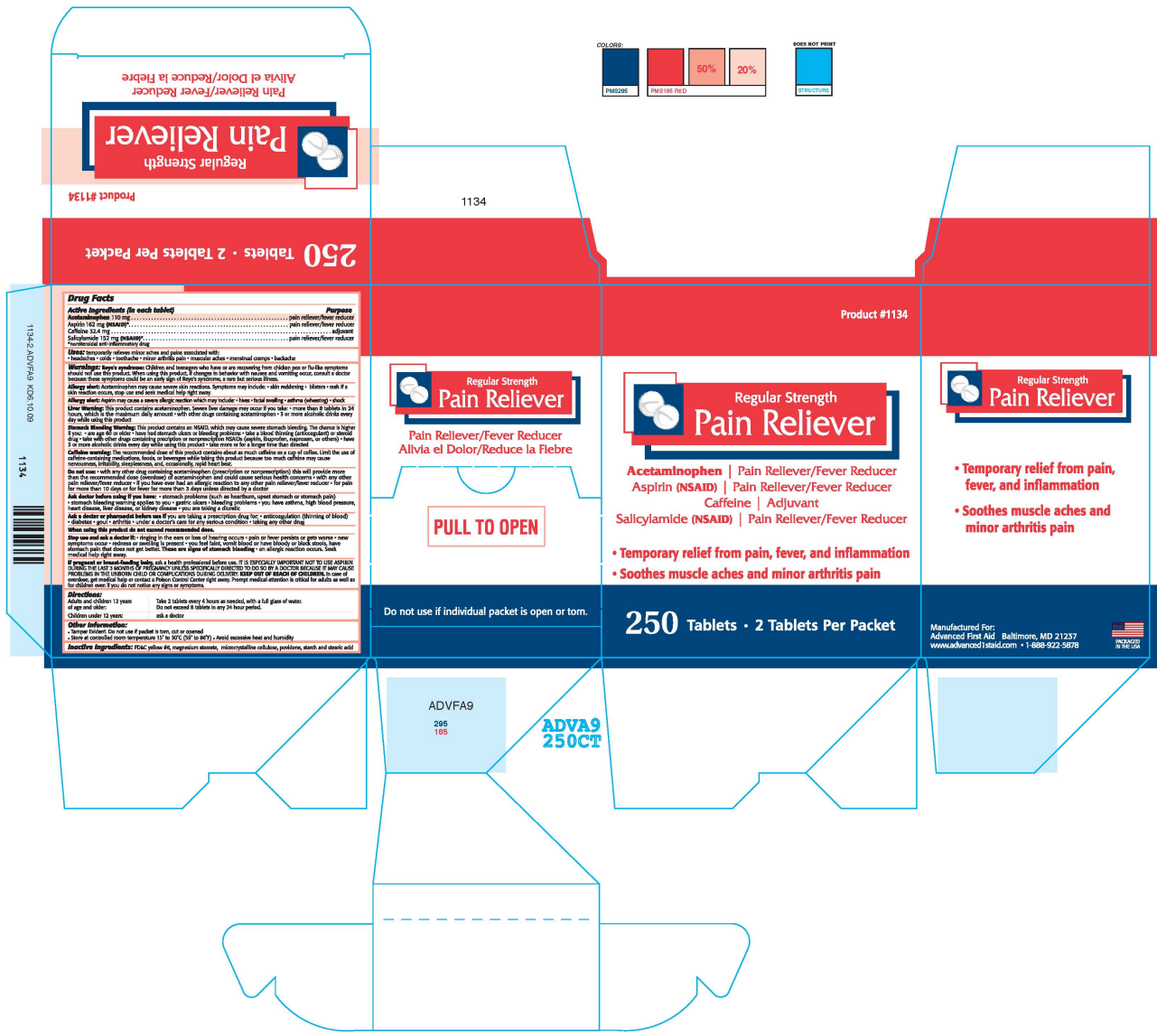
DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT

MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.

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.

Adults and children 12 years of age and older: Take 2 tablets every 4 hours as needed, with a full glass of water. Do not exceed 8 tablets in any 24 hour period.



PAIN RELIEVER

acetaminophen, aspirin, caffeine, salicylamide tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67060-113
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	110
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	162
SALICYLAMIDE (UNII: EM8BM710ZC) (SALICYLAMIDE - UNII:EM8BM710ZC)	SALICYLAMIDE	152
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.4

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	orange (ROSE ORANGE)	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	FR2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-113-67	250 in 1 CARTON	05/31/2019	
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	04/07/2015	

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-113)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA TAB LABORATORIES, INC.		151051757	manufacture(67060-113)