PAIN TERMINATOR- aspirin, acetaminophen, caffeine, salicylamide 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:

temporarily relieves minor aches and pains

associated with: • backache • toothache • colds • headaches • muscular aches • menstrual cramps • minor arthritis pain

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 □u symptoms

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

rare but serious illness reported to be associated with

aspirin.

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.

Do not use:• if you are allergic to aspirin • with any other pain reliever/fever reducer • 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

• with any other product containing acetaminophen

Ask a doctor before using if you have:

• asthma • gastric ulcers • bleeding problems • stomach problems (such as heartburn, upset stomach or stomach pain)

Ask a doctor or pharmacist before use if you are taking a prescription drug for: • anticoagulation (thinning of blood)

• diabetes • gout • arthritis

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

When using this product do not exceed

recommended dose.

Directions:

Adults and children 12 years of age and older take 2 tablets

every 4 hours for pain as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor.

Children under 12 years consult a doctor.

Inactive Ingredients:

FD&C yellow #6, magnesium stearate,

microcrystalline cellulose, povidone,

starch, and stearic acid.

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

PAIN RELIEVER, FEVER REDUCER WITH ADJUVANT

PAIN TERMINATOR

aspirin, acetaminophen, caffeine, salicylamide tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69103-2507
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CAFFEINE (UNII: 3G6A5W338E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	blue (SKY BLUE)	**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:69103-2507-5	250 in 1 CARTON	04/03/2015	07/01/2024
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69103-2507-6	100 in 1 CARTON	04/03/2015	07/01/2024
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	03/31/2015	07/01/2024

Labeler - Provision Medical Products (036936831)

Registrant - Provision Medical Products (036936831)

Establishment

Name	Address	ID/FEI	Business Operations
Ultraseal Corporation		085752004	pack(69103-2507)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(69103-2507)