

PAIN RELIEF MAXIMUM STRENGTH - acetaminophen, aspirin, caffeine tablet, coated
Select Corporation

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

Active Ingredients

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

Pain Reliever, Fever Reducer

Directions: Adults and children 12 years of age and older: 2 tablets as needed for pain every 6 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor. Children under 12 years: Consult a doctor

Uses: temporarily relieves minor aches and pains associated with:

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

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 use: • if you are allergic to aspirin or any other salicylate •

If you have ever had an allergic reaction to any other pain

reliever/fever reducer 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 nonprescription). Ask a doctor or pharmacist before

using with other drugs if you are not sure. • 3 or more alcoholic drinks

every day while using this product Stomach Bleeding Warning: This

product contains nonsteroidal antiinflammatory drugs (NSAIDs), which

may cause 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 an

NSAID (aspirin, ibuprofen, naproxen, or others). • Take more or for a

longer time than directed 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 doctor

before using if you have: • asthma • stomach problems (such as

heartburn, upset stomach or stomach pain) • gastric ulcers • bleeding

problems Ask a doctor or pharmacist before use if you are taking a

prescription drug for: • anticoagulation (thinning of blood) • diabetes •

gout • arthritis. 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

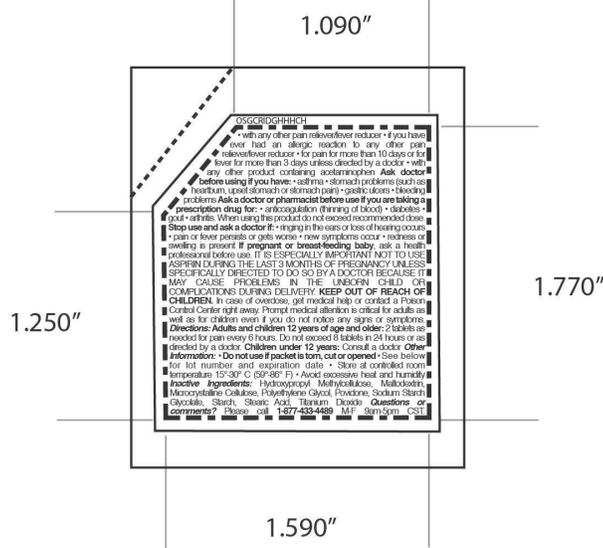
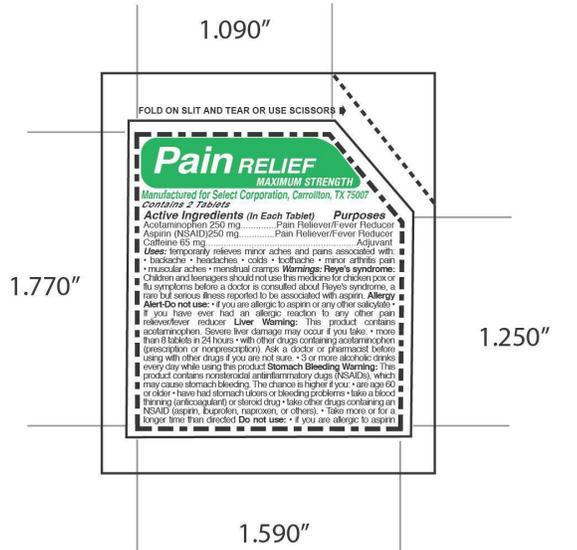
If pregnant or breast-feeding baby, ask a health professional before use. IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.

KEEP OUT OF REACH OF CHILDREN.

Inactive Ingredients: Hydroxypropyl Methylcellulose, Maltodextrin, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid, Titanium Dioxide

MM1

Pain Relief - Maximum Strength



acetaminophen, aspirin, caffeine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-468
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (snow white)	Score	no score
Shape	ROUND (FR9)	Size	12mm
Flavor		Imprint Code	FR9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-468-02	2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/15/2012	

Labeler - Select Corporation (053805599)