

PAIN RELIEF EXTRA STRENGTH - acetaminophen tablet
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 500mg

Analgesic, Antipyretic

Directions: Adults and children

12 years of age and older: • take 2 tablets every 4 to 6 hours as needed • do not take more than 8 tablets in 24 hours. Children under 12 years of age: • do not use this extra strength product; this will provide more than the recommended dose (overdose) and could cause serious health problems.

Uses: • temporary relief of minor aches and pains associated with • common cold • headache • backache • arthritis • toothache • muscular aches • menstrual cramps • and reduction of fever

Warnings:

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 Do not use: • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Ask a doctor before use if you have: liver disease. Ask a doctor or pharmacist before use if you are: taking the blood thinning drug warfarin. Stop use and ask a doctor if: • pain gets worse or lasts for more than 10 days • a rare sensitivity reaction occurs • fever gets worse or lasts more than 3 days • symptoms do not improve • new symptoms occur • redness or swelling is present. You may report side effects to 888-952-0050.

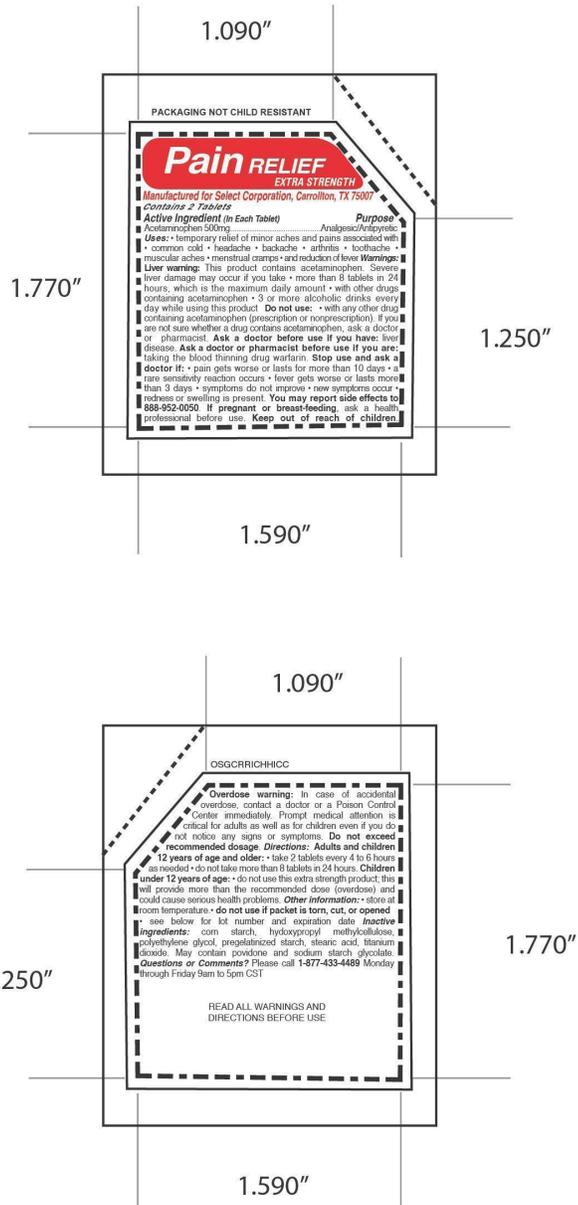
If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

Inactive ingredients: corn starch, hydroxypropyl methylcellulose, polyethylene glycol, pregelatinized starch, stearic acid, titanium dioxide. May contain povidone and sodium starch glycolate

MM1

Pain Relief - Extra Strength



acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-446
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

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

Product Characteristics

Color	white (snow white)	Score	no score
Shape	ROUND (AZ235)	Size	12mm
Flavor		Imprint Code	AZ235
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-446-02	2 in 1 PACKET		

Marketing Information

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

Labeler - Select Corporation (053805599)

Registrant - Select Corporation (053805599)