

PAIN RELIEF EXTRA STRENGTH EASY TO SWALLOW- acetaminophen 500 mg tablet
Allegiant Health

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 ingredient

Acetaminophen 500 mg

Purpose

Analgesic/Antipyretic

Uses

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

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4000 mg of acetaminophen 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

symptoms do not improve pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days new symptoms occur redness or swelling is present ■ a rare sensitivity reaction occurs You may report side effects to 1-888-952-0050

If pregnant or breast-feeding

ask a health professional before use

Keep Out of Reach of Children

In case of accidental overdose, contact a doctor or Poison Control Center immediately. Prompt medical

attention is critical for adults as well as for children even if you do not notice any signs or symptoms. Do not exceed recommended dosage.

Directions

Adults and children 12 years of age and older: Take 2 tablets (1,000 mg) every 6 hours while symptoms last. Do not take more than 6 tablets (3,000 mg) in 24 hours, unless directed by a doctor.

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.

Inactive Ingredients

carnauba wax, FD&C red #40 aluminum lake, hypromellose, polyethylene glycol(PEG) 400, polyethylene glycol (PEG) 8000, povidone, pregelatinized starch, stearic acid, sucralose, titanium dioxide.

Package/Label Principal Display Panel



PAIN RELIEF EXTRA STRENGTH EASY TO SWALLOW

acetaminophen 500 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 168 -353
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	
CARNAUBA WAX (UNII: R12CBM0EIZ)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
ALUMINUM OXIDE (UNII: LM26O6933)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POVIDONES (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	RED	Score	no score	
Shape	ROUND	Size	12mm	
Flavor		Imprint Code	TCL342	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-353-24	24 in 1 CARTON; Type 0: Not a Combination Product	12/17/2014	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part343		12/17/2014	

Labeler - Allegiant Health (079501930)

Registrant - Allegiant Health (079501930)

Establishment			
Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	ANALYSIS(69168-353) , LABEL(69168-353) , MANUFACTURE(69168-353) , PACK(69168-353) , RELABEL(69168-353) , REPACK(69168-353)