

NON-ASPIRIN ACETAMINOPHEN- non-aspirin acetaminophen tablet
Redicare LLC

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.

Acetaminophen (non-aspirin)

Active Ingredient (in each tablet)

Purpose

Acetaminophen 500 mgpain
reliever/fever reducer

Uses:

temporarily relieves minor aches and pains associated with ■ a headache ■ colds ■ a toothache ■ minor arthritis pain ■ muscular aches ■ menstrual cramps ■ a backache

Warnings:

Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if:
■ you take more than 8 tablets in 24 hours ■ you take with other drugs containing acetaminophen (prescription or non-prescription) ■ you have 3 or more alcoholic drinks every day while using this product.

Do not use:

■ with any other product containing acetaminophen ■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor

When using this product do not exceed recommended dose.

Stop use and ask a doctor if

■ symptoms do not improve ■ pain or fever persists or gets worse ■ new symptoms occur ■ redness or swelling is present

If pregnant or breast-feeding a baby,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

In a 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.

Directions:

Adults and children 12 years of age or older: Take 2 tablets every 4 to 6 hours as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor
 Children under 12 years of age: **Do not use this product:** this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns.

Other Information:

■ Tamper Evident. Do not use if packet is torn, cut or opened ■ Store at controlled room temperature 15° to 30°C (59° to 86°F) • Avoid excessive heat and humidity

Inactive Ingredients:

corn starch, microcrystalline cellulose, povidone, sodium starch glycolate, and stearic acid



NON-ASPIRIN ACETAMINOPHEN			
non-aspirin acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71105-210
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71105-210-68	100 in 1 CARTON; Type 0: Not a Combination Product	10/01/2017	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/01/2017	

Labeler - Redicare LLC (800149346)