ACETAMINOPHEN- acetaminophen tablet Rugby Laboratories

5427-Rugby

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

Temporarily reduces fever and relieves minor aches and pains caused by

- headache
- muscular aches
- the common cold
- toothache
- backache
- · minor pain of arthritis
- premenstrual and menstrual cramps

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash If a skin reaction occurs, stop use and seek medical help right away.

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.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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 more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

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

Keep out of reach of children.

Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see overdose warning)
 adults and children 12 years and over:
- take 2 tablets every 6 hours while symptoms last
- do not take more than 6 tablets in 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor

children under 12 years: ask a doctor

Other information

store in a dry place at 15° - 30°C (59° - 86°F).

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

Call 1-800-231-4670

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*Rugby Laboratories is not affiliated with the owner of the registered trademark Tylenol®.

Distributed by: RUGBY® LABORATORIES

Indianapolis, IN 46268

Questions or comments? Call (800) 616-2471 www.majorpharmaceuticals.com

Rugby

100 Tablets

COMPARE TO THE ACTIVE INGREDIENT IN EXTRA STRENGTH TYLENOL®* NDC 0536-1172-01

Extra Strength Acetaminophen

500mg each
Pain Reliever/Fever Reducer
Aspirin Free

FRONT OF LABEL



6.0"

NO COPY ADHESIVE ZONE

INSIDE OF LABEL take 2 tablets every 6 hours while symptoms last
 do not take more than 6 tablets in 24 hours, unless directed by a doctor
 do not take for more than 10 adults and children 12 years and over: Overdose warning: In case of overdose, get medica help or contact a Poison Control Center right away. Stop use and ask a doctor if • pain gets worse or lasts more than 10 days • lever gets worse or lasts more than 3 days • new symptoms occur • redness Keep out of reach of children. If pregnant or breast-feeding, ask a health Other information store in a dry place at 15° – 30°C (59° – 86°F). children under 12 years: ask a doctor days unless directed by a doctor Uirections
 do not take more than directed (see overdose Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin Ask a doctor before use if you have liver disease Drug Facts (continued Questions or comments? Call 1-800-231-4670 Inactive ingredients povidone, pregelatinized tarch, sodium starch glycolate, hese could be signs of a serious condition I-800-222-1222) Quick medical attention is critical swelling is present adults as well as for children even if you do not stearic

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0536-1172

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
	ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 ma	

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
POVIDONE K30 (UNII: U725QWY32X)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 585613G2A2)			

Product Characteris	duct Characteristics				
Color	white	Score	2 pieces		
Shape	ROUND	Size	12mm		
Flavor		Imprint Code	54;27		
Contains					

Ш	P	Packaging					
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date		
	1	NDC:0536-1172- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	11/30/2025		
l	2	NDC:0536-1172- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018			

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M013	10/01/2018			

Labeler - Rugby Laboratories (079246066)

Revised: 1/2024 Rugby Laboratories