ACETAMINOPHEN- acetaminophen tablet Proficient Rx LP

5427-Major

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 due to:

- headache □
- muscular aches □
- backache □
- minor pain of arthritis □
- common cold □
- toothache □
- 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.

- 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 \square

- 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 at room temperature

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

Call (800) 616-2471

SAVE CARTON FOR COMPLETE DRUG FACTS

Do not use if carton is open or if imprinted safety seal under cap is broken or missing.

Distributed By:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Repackaged By:

Proficient Rx LP

Thousand Oaks, CA 91320

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®

See New Warnings Information and Directions

Acetaminophen Extra Strength Tablets

Aspirin Free

Strong Pain and Fever Relief

Compare to active ingredient in Extra Strength Tylenol®*

30 tablets

500mg each





NDC 71205-165-30

Packaged By: Proficient Rx LP Thousand Oaks, CA 91320

71205116530

Acetaminophen 500mg

#30 ES Tablets

Each tablet contains: Acetaminophen 500 mg Pain reliever/ fever reducer

White, round, scored tablet with imprint code "54" and "27"

Product ID: QA016530

Dist. By: MAJOR PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA

Store at room temperature

Keep medication out of the reach of children

Acetaminophen 500mg #30 ES Tablets Lot #:00000 SN# MASTER NDC 71205-165-30 Exp:00/00/00

Acetaminophen 500mg #30 ES Tablets Lot #:00000 SN# MASTER NDC 71205-165-30 Exp:00/00/00

Acetaminophen 500mg #30 ES Tablets Lot #:00000 SN# MASTER NDC 71205-165-30 Exp:00/00/00



GTIN: 00371205165307 SN# MASTER Exp. 00/00/00 Lot #:00000

ACETAMINOPHEN

Product Information

acetaminophen tablet

r rouget information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-165(NDC:0904-6730)	

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg		

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
POVIDONE K30 (UNII: U725QWY32X)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-165- 10	10 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	
2	NDC:71205-165- 30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	
3	NDC:71205-165- 40	40 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	
4	NDC:71205-165- 50	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	
5	NDC:71205-165- 60	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	
6	NDC:71205-165- 90	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/12/2018	

Labeler - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-165), RELABEL(71205-165)

Revised: 2/2024 Proficient Rx LP