

ACETAMINOPHEN ES- pharbetol tablet
Contract Pharmacy Services-PA

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

"These highlights do not include all the information needed to use" "see full prescribing information for" "Initial U.S. Approval"

Active ingredient (in each tablet)

Acetaminophen 500mg

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains due to:

- headache
- backache
- minor pain of arthritis
- toothache
- muscular aches
- menstrual cramps

Temporarily reduces 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
- 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 and ask doctor before use 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 doctor before use.

Keep out of reach of children.

Directions

- **do not take more than directed (see overdose warning).**
- **Adult and Children 12 years and over:** take 2 tablets, every 4 to 6 hours while symptoms last. Do not take more than 8 tablets in 24 hours. Do not take for more than 10 days unless directed by a doctor.
- **Children under 12 years:** do not use adult extra strength product in children under 12 years of age; this will provide more than recommended dose (overdose) and may cause liver damage.

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away.

Inactive ingredients

Povidone, Pregelatinized corn starch, sodium starch glycolate, stearic acid.

Questions?

Adverse drug event call: (866) 562-2756

ACETAMINOPHEN ES
500 MG CPLT #60



016103350119

LOT: xxx
PILL ID: PH016
EXP: 04/18/19
PHARBEST

Packaged By: Contract Pharmacy Services-PA
125 Titus Ave, Suite #200, Warrington, PA 18976

Usual Adult Dosage: Take 2
caplets every 4 to 6 hours;
Do not take more than 8
caplets in 24 hours.



0 16103 35011 9

Store between 68-77°F (20-25°C)

Each caplet contains: Acetaminophen 500 mg

CPS NDC: 67046-028-60

ACETAMINOPHEN ES 2/b/s
500 MG CPT #30x2



016103350119

LOT: xxx
PILL ID: PH016
EXP: 04/18/19
PHARBEST

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125 Titus Ave, Suite #200, Warrington, PA 18976

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0 16103 35011 9

Store between 68-77°F (20-25°C)

Each caplet contains: Acetaminophen 500 mg

CPS NDC: 67046-028-62

ACETAMINOPHEN ES
500 MG CPLT #30



016103350119

LOT: xxx
PILL ID: PH016
EXP: 04/18/19
PHARBEST

Packaged By: Contract Pharmacy Services-PA
125 Titus Ave, Suite #200, Warrington, PA 18976

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Each caplet contains: Acetaminophen 500 mg

CPS NDC: 67046-028-30

ACETAMINOPHEN ES

pharbetol tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-028(NDC:16103-376)
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
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	PH044
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-028-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/10/2006	
2	NDC:67046-028-60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/10/2006	
3	NDC:67046-028-62	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/10/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/10/2006	

Labeler - Contract Pharmacy Services-PA (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 4/2018

Contract Pharmacy Services-PA