

**EXTRA STRENGTH ACETAMINOPHEN- extra strength acetaminophen 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.*

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**Extra Strength Acetaminophen Tablets**

**DRUG FACTS**

**ACTIVE INGREDIENT (IN EACH CAPLET)**

**Acetaminophen Caplets, 500 mg**

**PURPOSE**

Pain reliever/fever reducer

**USES**

- temporarily reduces fever
- temporarily relieves minor aches and pains due to:
  1. headache
  2. muscular aches
  3. the common cold
  4. minor pain of arthritis
  5. backache
  6. toothache
  7. premenstrual and menstrual cramps

**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 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: Taking more than the recommended dose (overdose) may cause liver damage. 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**

- 
- |                                       |   |
|---------------------------------------|---|
| adults and children 12 years and over | <ul style="list-style-type: none"><li>• take 2 tablets every 4 to 6 hours while symptoms last</li><li>• do not take more than 8 tablets in 24 hours</li><li>• do not take for more than 10 days unless directed by a doctor</li></ul> |
|---------------------------------------|---|

do not use adult Extra Strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

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**OTHER INFORMATION**

store at 15° to 30°C (59° to 86°F)

**INACTIVE INGREDIENTS**

povidone, pregelatinized starch, stearic acid

**QUESTIONS OR COMMENTS?**

Distributed by: Major Pharmaceuticals, 31778 Enterprise Drive, Livonia, MI 48150, U.S.A.

call toll free **734-743-6000**

Repackaged by:

Contract Pharmacy Services-PA  
125 Titus Ave Suite 200  
Warrington, PA 18976 USA

Original--08/2010--NJW

**Package Label**

**ACETAMINOPHEN ES 2/bis**

500MG CAP#30x2



64200010000915

LOT# SAMPLE  
ID: GPI A5  
EXP: 04/11

MAJOR

USUAL DOSAGE:  
SEE INSERT

STORAGE  
CONDITIONS. SEE  
INSERT  
(STORE AT  
CONTROLLED ROOM  
TEMPERATURE)

FILLED BY \_\_\_\_\_

CHECKED BY \_\_\_\_\_

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

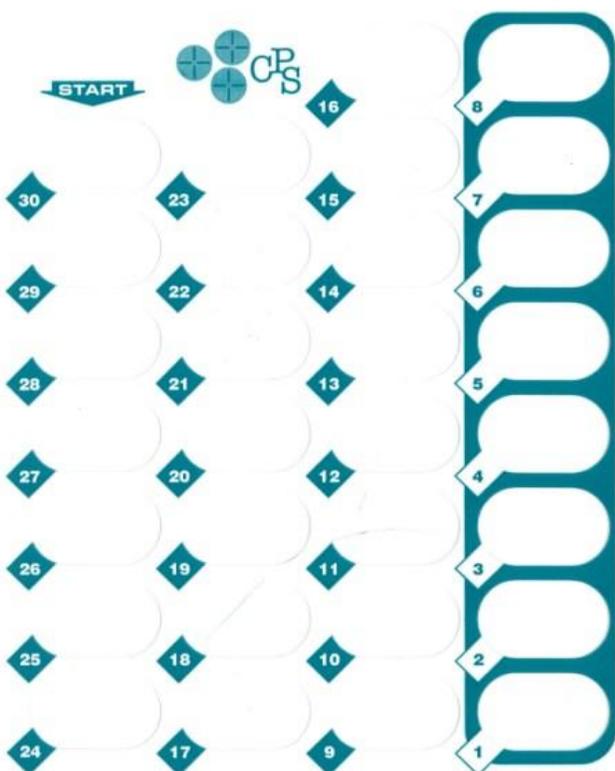
MED. \_\_\_\_\_

STRENGTH \_\_\_\_\_

EXP. DATE \_\_\_\_\_

MFG. \_\_\_\_\_

LOT NO. \_\_\_\_\_



CAUTION: This package NOT CHILD RESISTANT. Store this and all medications out of reach of children.

**500 mg Tablets**

**EXTRA STRENGTH ACETAMINOPHEN**

extra strength acetaminophen tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67046-026(NDC:0904-1983)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL ((capsule-shaped))	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-026-30	30 in 1 BLISTER PACK		
2	NDC:67046-026-60	60 in 1 BLISTER PACK		
3	NDC:67046-026-62	60 in 1 BLISTER PACK		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/02/2010	

**Labeler** - Contract Pharmacy Services-PA (945429777)

Revised: 7/2010

Contract Pharmacy Services-PA