# ACETAMINOPHEN- 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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## **Acetaminophen Tablets**

#### **DRUG FACTS**

## ACTIVE INGREDIENT (IN EACH TABLET)

## Acetaminophen Tablets, 325mg

#### **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

- take 2 tablets every 4 to 6 hours while symptoms last
- children do not take more than 8 tablets in 24 hours
  - do not take for more than 10 days unless directed by a doctor

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

### 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.

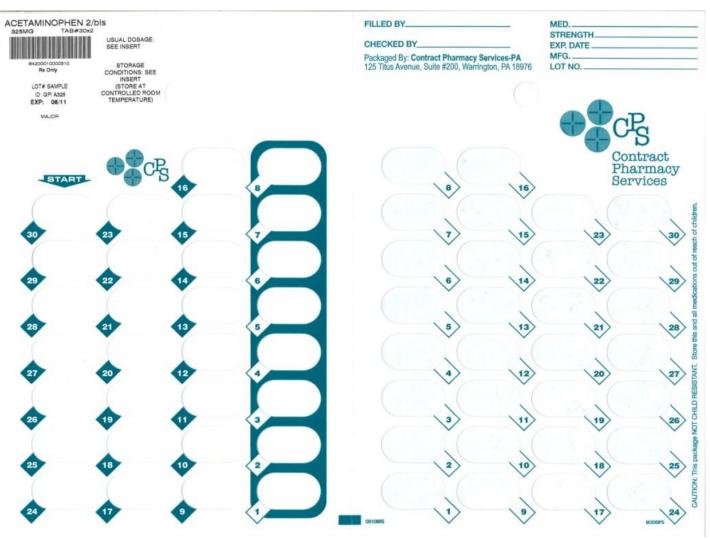
call toll free **734-743-6000** 

Repackaged by:

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

Original--08/2010--NJW

## **Package Label**



## 325 mg Tablets

## **ACETAMINOPHEN**

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-024(NDC:0904-1982)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	

Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-024-30	30 in 1 BLISTER PACK		
2	NDC:67046-024-60	60 in 1 BLISTER PACK		
3	NDC:67046-024-62	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