

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.

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">• 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 |
|---------------------------------------|---|

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: Marlex Pharmaceuticals, 50 McCullough Drive, New Castle, DE 19720, U.S.A.

call toll free **1-866-820-7381**

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



842001 000315

LOT# SAMPLE
ID: M2A4 87344
EXP: 03/12

MARLEX

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 _____

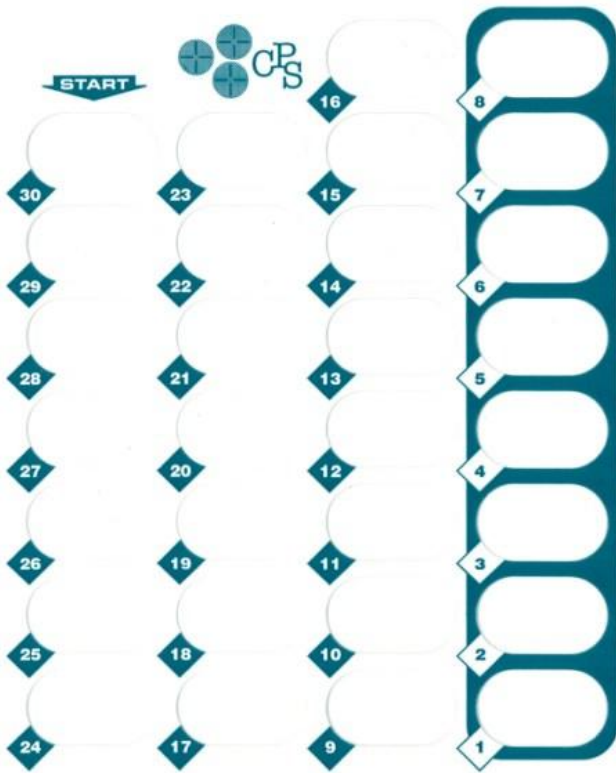
EXP. DATE _____

MFG. _____

LOT NO. _____



Contract
Pharmacy
Services



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

500 mg Caplets

EXTRA STRENGTH ACETAMINOPHEN

extra strength acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-027(NDC:10135-144)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-027-30	30 in 1 BLISTER PACK		
2	NDC:67046-027-60	60 in 1 BLISTER PACK		
3	NDC:67046-027-62	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