ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet
Physicians Total Care, Inc.

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.

Acetaminophen Tablets
Extra Strength

*Compared to the active ingredient in Extra Strength Tylenol®

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Acetaminophen 500 mg

PURPOSES

Pain Reliever/Fever Reducer

USES

For the temporary relief of minor aches and pains due to:

- Headache
- Muscular aches
- Backache
- Minor pain of arthritis
- The common cold
- Toothache
- Premenstrual and menstrual cramps

Temporarily reduces fever.

WARNINGS

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 caplets 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 the 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.

Adults and children 12 years and over:

- Take 2 caplets every 4 to 6 hours while symptoms last
- Do not take more than 8 caplets 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 the recommended dose (overdose) of acetaminophen and may cause liver damage.

OTHER INFORMATION

- Store at room temperature 15°-30°C (59°-86°F)
- Use by expiration date on package

INACTIVE INGREDEINTS

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid

Questions? To report a Serious Adverse Event contact 1-877-835-5472.

*This product is not manufactured or distributed by McNeil Consumer Products Co., owners of the registered trademark Tylenol®.

Distributed by:

Amneal Pharmaceuticals

104 Hippocrates Way,

Glasgow, KY 42141

Rev. 11/2009

Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

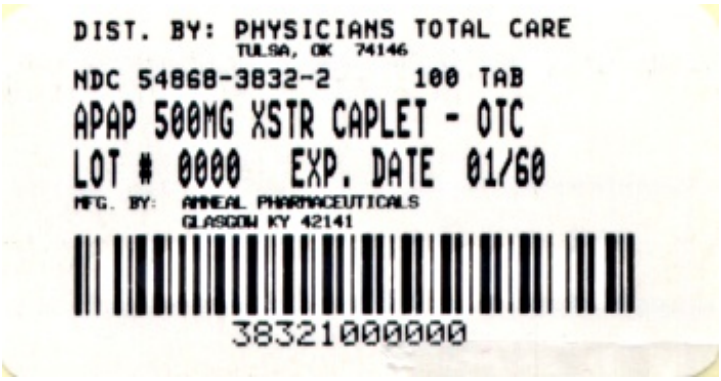
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Acetaminophen
Caplets

Extra Strength

500 mg

NDC 54868-3832-1



Keep out of reach of children.

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-3832(NDC:65162-607)
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 (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	6mm
Flavor		**Imprint Code**	GPI;A5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3832-0	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	10/24/2002	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-3832)

Revised: 9/2012 Physicians Total Care, Inc.