

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.

Active Ingredients

Acetaminophen 500 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains
- 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.

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 symptom 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.

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Keep out of reach of children.

Directions

- **do not take more than directed**
- adults and children 12 years and over: take 1-2 tablets every 4-6 hours, as needed; not more than 8 tablets in 24 hours

- children under 12 years: do not use

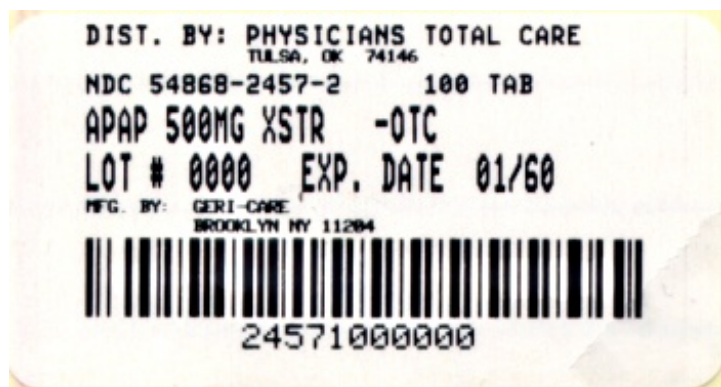
Other Information

- **TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.**
- store at 20°C-25°C (68°F-77°F)
- for institutional use only

Inactive Ingredients

povidone, sodium starch glycolate, starch stearic acid. May also contain: crospovidone, methylparaben and propylparaben

NDC 54868-2457-2



SEE NEW WARNINGS

Non-Aspirin

Extra Strength

PAIN RELIEF

Acetaminophen Tablets

*Compare to active ingredient in Extra Strength Tylenol Tablets

PACKAGE NOT CHILD RESISTANT

500 mg each

Dist. By: Gericare Pharmaceuticals Corp.
1650 63rd Street, Brooklyn, NY 11204

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

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-2457(NDC:57896-201)	
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)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
CROSPVIDONE (UNII: 68401960MK)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
Product Characteristics				
Color	white (WHITE)	Score	no score	
Shape	ROUND (Round)	Size	12mm	
Flavor		Imprint Code	M2A457344	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-2457-2	100 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	08/22/2002		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel