EXTRA STRENGTH PAIN RELIEF- acetaminophen capsule, gelatin coated Geri-Care Pharmaceutical Corp

251

Active ingredient (in each gelcap)

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 gelcaps (4,000 mg of acetaminophen) in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions.

Symptoms may include: • skin reddening • blisters • rash

If a skin reaction occurs, stop use and seek medical help right away.

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. 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 gelcaps every

6 hours, as needed; not more than 6 gelcaps in 24 hours. Do not take for more than 10 days unless directed by a doctor.

children under 12 years: ask a doctor

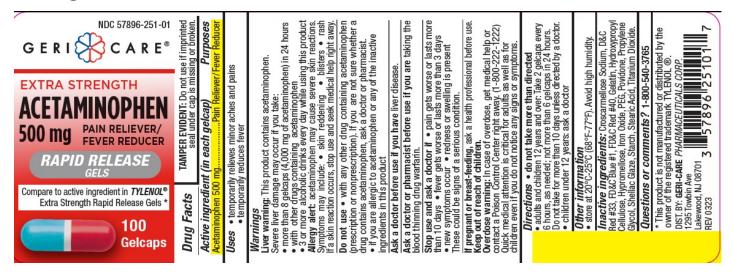
Other Information

- store at 20°C-25°C (68°F-77°F)
- avoid high humidity

Inactive Ingredients

Croscarmellose Sodium, D and C Red 33, FD and C Blue 1, FD and C Red 40, Gelatin, Hydroxypropyl Cellulose, Hypromellose, Iron Oxide, PEG, Povidone, Propylene Glycol, Shellac Glaze, Starch, Stearic Acid, Titanium Dioxide.

Package label



EXTRA STRENGTH PAIN RELIEF

acetaminophen capsule, gelatin coated

decidifilitophen capsale, gelatin coated					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:5789	96-251
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Active ingredient/Active	Molecy				
Ingr	edient Name		Basis of St	rength	Strength

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GELATIN (UNII: 2G86QN327L)		
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SHELLAC (UNII: 46N107B710)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		

Product Characteristics			
Color	red (red, gray and blue)	Score	no score
Shape	CAPSULE (Gelcap)	Size	19mm
Flavor		Imprint Code	L5
Contains			

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:57896-251- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2012		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/01/2007	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)