EXTRA STRENGTH PAIN RELIEF- acetaminophen tablet
Geri-Care Pharmaceutical Corp

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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gc221

Active ingredient

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 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.

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 caplets every 4-6 hours, as needed; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

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 probylparaben

Package label

GERICARE

NDC 57896-221-01

Non-Aspirin

Extra Strength

PAIN RELIEF

Acetaminophen Caplets

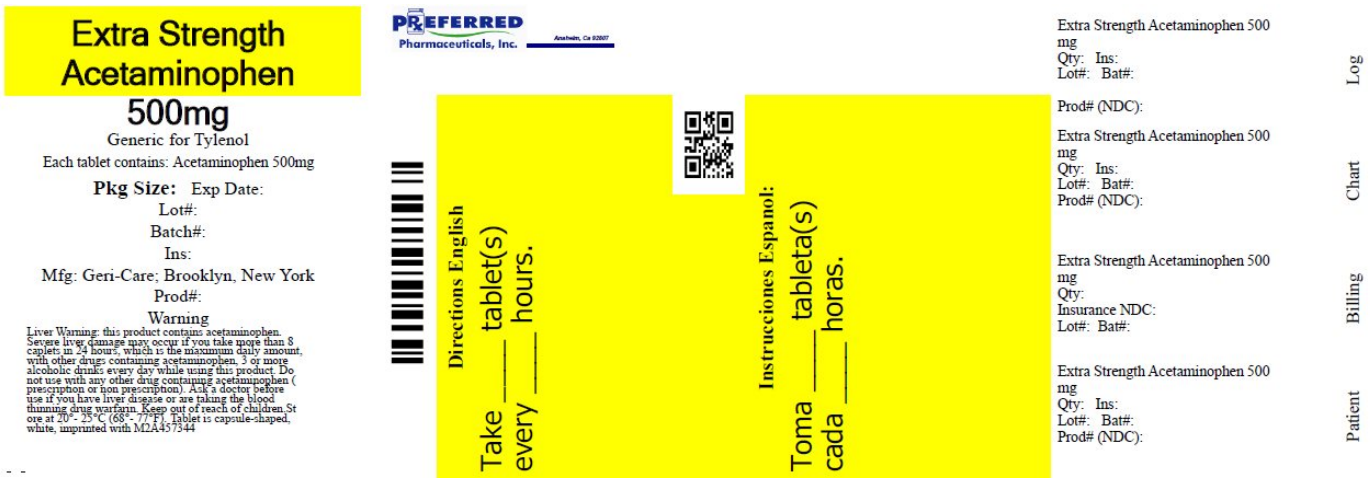
Pain Reliever / Fever Reducer

Compare to active ingredients in Extra Strength Tylenol Caplets*

PACKAGE NOT CHILD RESISTANT

Caplets 500 mg

Repackaged By: Preferred Pharmaceuticals Inc.



EXTRA STRENGTH PAIN RELIEF

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-7620(NDC:57896-221)
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, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics			
Color	white (WHITE)	**Score**	no score
Shape	CAPSULE (Capsule)	**Size**	15mm
Flavor		**Imprint Code**	M2A457344
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68788-7620-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	

2	NDC:68788-7620-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
3	NDC:68788-7620-4	45 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
4	NDC:68788-7620-5	50 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
5	NDC:68788-7620-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
6	NDC:68788-7620-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/18/2020	

Labeler - Geri-Care Pharmaceutical Corp (791119022)

Registrant - Geri-Care Pharmaceutical Corp (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceutical Corp		791119022	REPACK(68788-7620)

Revised: 5/2020 Geri-Care Pharmaceutical Corp