

EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet
Geri-Care Pharmaceutical Corp

gc204

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 (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.

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..

Keep out of reach of children. 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 1-2 tablets every 4-6 hours, as needed; not more than 6 tablets 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


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

Inactive Ingredients

povidone, sodium starch glycolate, starch, stearic acid.

Questions or comments?

1-800-540-3765

 <p>NDC 57896-204-01</p> <p>EXTRA STRENGTH ACETAMINOPHEN 500 mg</p> <p>PAIN RELIEVER/ FEVER REDUCER</p> <p>Compare to the active ingredient in Extra Strength TYLENOL® *</p> <p>100 Tablets 500 mg each</p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet) Acetaminophen 500 mg.....Pain Reliever/Fever Reducer</p> <p>Uses</p> <ul style="list-style-type: none"> • temporarily relieves minor aches and pains • temporarily reduces fever <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> • more than 8 tablets (4,000 mg of acetaminophen) in 24 hours • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product <p>Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>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.</p> <p>Ask a doctor before use if you have liver disease.</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • 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 <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. 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.</p>	<p>Directions • do not take more than directed</p> <ul style="list-style-type: none"> • adults and children 12 years and over: take 1-2 tablets every 4-6 hours, as needed; not more than 6 tablets in 24 hours. Do not take for more than 10 days unless directed by a doctor. • children under 12 years: ask a doctor <p>Other information • TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.</p> <ul style="list-style-type: none"> • store at 20°C-25°C (68°F-77°F) <p>Inactive ingredients: povidone, sodium starch glycolate, starch, stearic acid.</p> <p>Questions or comments? 1-800-540-3765</p> <p>* This product is not manufactured or distributed by the owner of the registered trademark TYLENOL®. DIST. BY: GERI-CARE PHARMACEUTICALS CORP. 1650 63rd Street, Brooklyn, NY 11204</p> <p>3 57896 20101 2</p> <p>REV 0621AI</p>
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EXTRA STRENGTH ACETAMINOPHEN
acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-204
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (WHITE)	Score	no score
Shape	ROUND (Round)	Size	12mm
Flavor		Imprint Code	AZ011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-204-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
2	NDC:57896-204-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
3	NDC:57896-204-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
4	NDC:57896-204-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2018	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023

Geri-Care Pharmaceutical Corp