

EXTRA STRENGTH PAIN RELIEF- acetaminophen tablet, coated
Chain Drug Consortium, LLC

premier value 251

Active ingredient

Acetaminophen 500 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains due to:
 - - headache
 - - muscular aches
 - - backache
 - - arthritis
 - - the common cold
 - - toothache
 - - menstrual cramps
- temporarily reduces fever

Warnings

Liver warning:

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

- more than 8 gels 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 (see overdose warnings)**

Adults and children 12 years and over	<ul style="list-style-type: none"> ◦ Take 2 gelcaps every 4-6 hours, as needed. ◦ Do not take more than 8 gelcaps 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 controlled room temperature 20°C-25°C (68°F-77°F)
- avoid high humidity

Inactive Ingredients

croscarmellose sodium, D&C Red #33, FD&C Blue #1, FD&C Red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide, PEG, povidone, propylene glycol, shellac glaze, starch, stearic acid, titanium dioxide.

package label

NDC 68016-029-47

Compare to active ingredient in Extra Strength Tylenol Rapid Release Gels*

Extra Strength

PAIN RELIEF

ACETAMINOPHEN

Rapid Release

Pain Reliever/ Fever Reducer

Gelcaps

400 Gelcaps
500 mg each

NDC 68016-029-47
COMPARE TO THE ACTIVE
INGREDIENT IN EXTRA
STRENGTH TYLENOL®
RAPID RELEASE GELS*



**EXTRA
STRENGTH**

Pain Relief

ACETAMINOPHEN • RAPID RELEASE

PAIN RELIEVER/FEVER REDUCER

Gelcaps



**400 Gelcaps
500 mg each**



<p>Drug Facts</p> <p>Active Ingredient (in each gelcap) Purposes Acetaminophen 500 mg.....Pain Reliever/Fever Reducer</p> <p>Uses • temporarily relieves minor aches and pains due to: • headache • muscular aches • backache • arthritis • the common cold • toothache • menstrual cramps • temporarily reduces fever</p> <p>Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 8 gelcaps 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</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. 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: • 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.</p> <p>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. ▶</p>	<p>Drug Facts (continued)</p> <p>Directions • Do not take more than directed (see overdose warning)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Adults and children 12 years and over</td> <td>• Take 2 gelcaps every 4 to 6 hours as needed • Do not take more than 8 gelcaps in 24 hours</td> </tr> <tr> <td>Children under 12 years</td> <td>Do not use</td> </tr> </table> <p>Other information • Tamper Evident: Do not use if imprinted seal under cap is missing or broken. • store at controlled room temperature 20°-25°C (68°-77°F) • avoid high humidity</p> <p>Inactive Ingredients: Croscarmellose Sodium, D&C Red #33, FD&C Blue #1, FD&C Red #40, Gelatin, Hydroxypropyl Cellulose, Hypromellose, Iron Oxide, PEG, Povidone, Propylene Glycol, Shellac Glaze, Starch, Stearic Acid, Titanium Dioxide.</p> <p>*This product is not manufactured or distributed by the owner of the registered trademark TYLENOL®. REV GC251-1112</p> <p>DISTRIBUTED BY: Chain Drug Consortium, LLC. 3301 N.W. Boca Raton Blvd., Suite 101, BOCA RATON, FL 33431</p> <div style="text-align: right;">  8 40986 01993 7 </div>	Adults and children 12 years and over	• Take 2 gelcaps every 4 to 6 hours as needed • Do not take more than 8 gelcaps in 24 hours	Children under 12 years	Do not use
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EXTRA STRENGTH PAIN RELIEF

acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-029
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	red (with blue and a gray band)	Score	no score
Shape	CAPSULE (Gelcap)	Size	19mm
Flavor		Imprint Code	L;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-029-20	1 in 1 CARTON	09/01/2007	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68016-029-14	1 in 1 CARTON	09/01/2007	08/31/2022
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68016-029-47	400 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2007	04/30/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/01/2007	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023

Chain Drug Consortium, LLC