

**ACETAMINOPHEN- acetaminophen tablet, extended release**  
**GERI-CARE PHARMACEUTICAL CORP**

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**hst 265 (268)**

**ACTIVE INGREDIENT (IN EACH CAPLET)**

Acetaminophen USP, 650 mg

**PURPOSE**

Pain reliever/fever reducer

**USES**

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

**WARNINGS**

**Liver warning:** This product contains acetaminophen. Severe Liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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 drugs 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 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:** In case of overdose, get medical help or contact a poison control center right away.(1-800 222-1222). 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 (see overdose warning)**

**Adults:** • take 2 caplets every 8 hours with water  
• swallow whole; do not crush, chew, split or dissolve  
• do not take more than 6 caplets in 24 hours  
• do not use for more than 10 days unless directed by a doctor

**Under 18 years of age:** ask a doctor

**OTHER INFORMATION**

- store between 20-25°C (68-77°F)

**INACTIVE INGREDIENTS**

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**QUESTIONS OR COMMENTS ?**

**1-800-540-3765**

**PRINCIPAL DISPLAY PANEL**



NDC 57896-268-01

THE SENSIBLE CHOICE FOR PRICE AND HEALTH

## ARTHRITIS PAIN RELIEF

**ACETAMINOPHEN**

EXTENDED-RELEASE TABLETS USP, 650 mg

PAIN RELIEVER/FEVER REDUCER

For the Temporary Relief of Minor Arthritis Pain Lasts up to 8 hours. Use as directed.

Compare to active ingredient in 8 Hour **TYLENOL®** Arthritis Pain\*\*

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

**100 Caplets\* 650 mg each**  
(\*Capsule-Shaped Bi-Layer Tablets)**TAMPER EVIDENT:** Do not use if imprinted seal under cap is missing or broken.**Drug Facts****Purpose**  
**Active ingredient (in each caplet)**  
Acetaminophen USP, 650 mg.....Pain reliever/fever reducer**Uses**  
• temporarily relieves minor aches and pains due to:  
• minor pain of arthritis • muscular aches • backache • toothache  
• premenstrual and menstrual cramps • the common cold • headache  
• temporarily reduces fever**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:  
• more than 6 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**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:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 (see overdose warning)**Adults:** • take 2 caplets every 8 hours with water.  
• swallow whole; do not crush, chew, split or dissolve  
• do not take more than 6 caplets in 24 hours  
• do not use for more than 10 days unless directed by a doctor**Under 18 years of age:** ask a doctor**Other information** • store between 20° - 25° C (68° - 77° F)**Inactive ingredients:** hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.**Questions or comments? 1-800-540-3765**  
\*\* This product is not manufactured or distributed by the owner of the registered trademark TYLENOL®.MADE IN INDIA  
REV 0719G  
DIST. BY: GRI-CARE PHARMACEUTICALS CORP.  
1650 63rd Street  
Brooklyn, NY 11204  
3 57896 126501 4**ACETAMINOPHEN**

acetaminophen tablet, extended release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57896-268
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

**Inactive Ingredients**

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) (UNII: 8136 Y38 GY5)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19 mm
<b>Flavor</b>		<b>Imprint Code</b>	G650
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-268-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	07/01/2019	

**Labeler** - GERI-CARE PHARMACEUTICAL CORP (611196254)**Registrant** - GERI-CARE PHARMACEUTICAL CORP (611196254)

Revised: 9/2019

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