

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

hst 265 (268)

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen 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

HEALTH STAR

8 HOUR ARTHRITIS PAIN

ACETAMINOPHEN

EXTENDED-RELEASE TABLETS USP, 650 mg
PAIN RELIEVER/FEVER REDUCER
For the Temporary Relief of Minor Arthritis Pain

Compare to active ingredient in
TYLENOL® 8HR Arthritis Pain*

**DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN**

100 Caplets 650 mg each**
(**Capsule-Shaped Bi-Layer Tablets)

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts	Active ingredient (in each caplet) Acetaminophen 650 mg	Purpose Pain reliever/fever reducer
	Uses temporarily relieves minor aches and pains due to: ■ minor pain of arthritis ■ muscular aches ■ backache ■ headache ■ the common cold ■ headache ■ premenstrual and menstrual cramps ■ temporarily reduces fever	
	Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ with other drugs containing acetaminophen ■ more than 6 caplets in 24 hours, which is the maximum daily amount ■ 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 ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present	
	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) ■ 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	
	*This product is not manufactured or distributed by the distributor of Tylenol® 8HR Arthritis Pain. Made in India DIST. BY: GERRI-CARE PHARMACEUTICALS CORP. R022A L1200A12HST_R1 1295 Towbin Ave., Lakewood, NJ 08701	



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ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-268
Route of Administration	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 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (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: 4ELV7Z 65AP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G650
Contains			

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: 7/2024

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