ACETAMINOPHEN- acetaminophen tablet MAJOR PHARMACEUTICALS

Acetaminophen Extended-Release Tablets USP, 650mg Pain Reliever/Fever Reducer

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

Liver 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

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
- \blacksquare 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)
■ do not use if foil inner seal is broken or missing

Inactive ingredients

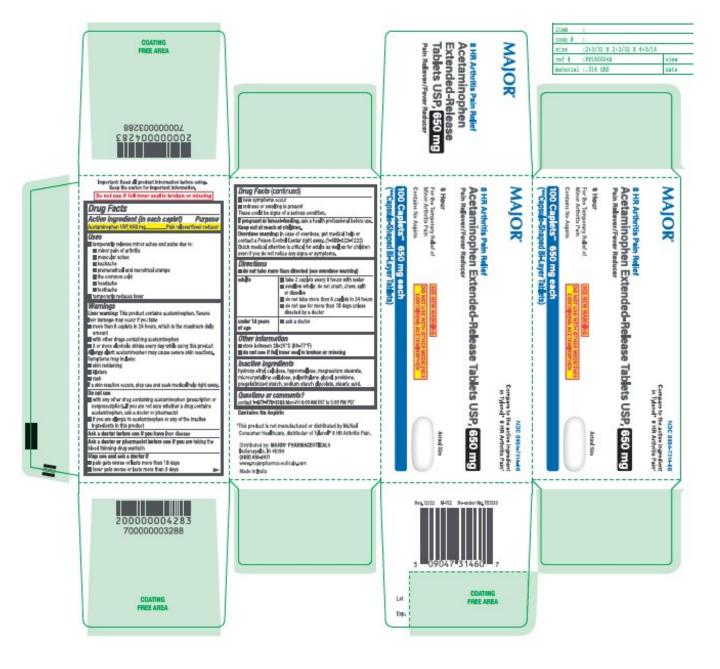
hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?

contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP

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00 Caplets** 650 mg each *Capsule-Shaped Bi-Layer Tablets)	Drug Active	USSES torup bit to to to to to to to	Warrs Ulwer w mere with c 3 or n 3 or n 3 or n Allergy	Surth and with a sure sure sure sure sure sure sure sure	Pan g there there here here construction cover to vou do r	Direc adults under 1	Other store for me francti hydraxy	Quest Quest Contact Contact Distribute (rec) rite (rec) rite	Alade in Man



ACETAMINOPHEN						
acetaminophen tablet						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sou	irce)	NDC:090	4-7314	
Route of Administration	ORAL					
Active Ingredient/Active	Moiety					
Ingre	edient Name		Basis of St	rength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN					650 mg	
Inactive Ingredients						
	Ingredient Name			9	Strength	

HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: 08232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white (WHITE TO OFF WHITE COLORED)	Score	no score
Shape	OVAL (CAPSULE SHAPED, BICONVEX INTACT FILM COATED TABLETS)	Size	19mm
Flavor		Imprint Code	G;650
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7314- 27	400 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023	
	NDC:0904-7314- 60	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	03/03/2023	

Labeler - MAJOR PHARMACEUTICALS (191427277)

Revised: 11/2024

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