#### ACETAMINOPHEN- acetaminophen tablet MAJOR PHARMACEUTICALS

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#### 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

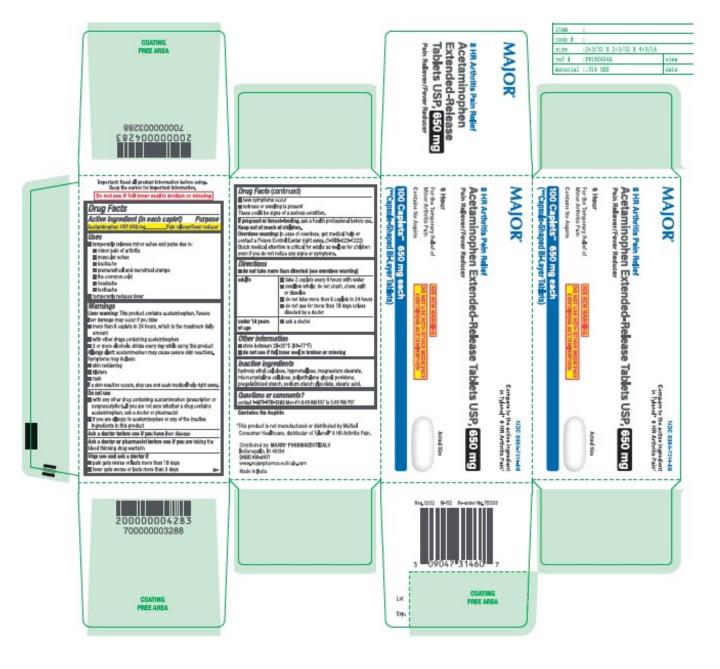
hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

#### **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						
<b>Product Information</b>						
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

MAJOR PHARMACEUTICALS