# ACETAMINOPHEN EXTENDED RELEASE- acetaminophen tablet Rite Aid Corporation

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**Drug Facts** 

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
  - backache
  - muscular aches
  - toothache
  - premenstrual and menstrual cramps
  - headache
  - the common cold
- 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 ever 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 a 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. 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
  - o 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?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

## **Principal Display Panel**

Compare to the active ingredient of Tylenol® 8 HR Arthritis Pain

SEE NEW WARNING

8 HR ARTHRITIS PAIN RELIEF

**ACETAMINOPHEN** 

EXTENDED-RELEASE TABLETS USP 650 mg

PAIN RELIEVER/FEVER REDUCER

For the temporary relief of minor arthritis pain

Contain no aspirin

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

**CAPLETS** 

\*CAPSULE-SHAPED BI-LAYER TABLETS

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8 HR Arthritis Pain.

TAMPER EVIDENT: DO NOT USE IF FOIL INNER SEAL IS BROKEN OR MISSING.

### **DISTRIBUTED BY:**

RITE AID, 30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

#### **Product Label**



Overdose warning: in case of overdose, get medical help or contact a Poison Contro Center (1-800-222-1222) right away. Quick medical attention is critical for adults as pain gets worse or lasts more than 10 days lever gets worse or lasts more than 3 days Questions or comments? Call 1-877-753-3935 Monday-Friday ■ do not take more than directed (see Overdose warning) If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. new symptoms occur Ask a doctor or pharmacist before use if you are taking the blood thinning drug Ask a doctor before use if you have liver disease Drug Facts (continued) nactive ingredients Other information radness or swelling is present These could be signs of a serious condition. under 18 years of age: ask a doctor um starch glycolate, do not take more take 2 caplets every 8 hours with water use and ask a doctor if use for more than 10 days unless directed by a doctor than 6 capiets in 24 hours m Store Detween hydroxyethyl cellulose, hypromellose, magnesium do not notice any signs or sym chew, split, or dissolve 9WI-5PM EST glycot, povidone, pregalatinized starch

#### **RITE AID PHARMACY Acetaminophen Extended-Release Tablets**

## ACETAMINOPHEN EXTENDED RELEASE acetaminophen tablet **Product Information HUMAN OTC DRUG** NDC:11822-6304 **Product Type** Item Code (Source) **Route of Administration ORAL Active Ingredient/Active Moiety Basis of Strength** Strength Ingredient Name ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) **ACETAMINOPHEN** 650 mg **Inactive Ingredients Ingredient Name** Strength HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:11822- 6304-1	1 in 1 BOX	05/29/2020	05/29/2025		
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:11822- 6304-3	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2020	05/29/2025		
3	NDC:11822- 6304-2	1 in 1 BOX	05/29/2020	05/29/2025		
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA211544	05/29/2020	05/29/2025	

## Labeler - Rite Aid Corporation (014578892)

Revised: 11/2022 Rite Aid Corporation