

ACETAMINOPHEN- acetaminophen tablet, film coated, extended release RITE AID

8HR Arthritis Pain Relief

Acetaminophen

Extended-Release Tablets USP, 650mg

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 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 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
 - 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



ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11822-5019

Route of Administration		ORAL	
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Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	650 mg

Inactive Ingredients	
Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	

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				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5019-4	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	11/30/2021	

Labeler - RITE AID (014578892)