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

8 HR 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 childrern

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

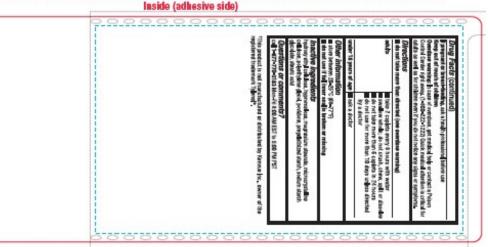
PDP







o simulate a printed label, fold along dotted line.



ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

_			
Dra	HIICT.	Inform	ation

HUMAN OTC DRUG Product Type Item Code (Source) NDC:11822-5091

Route of Administration ORAL

Active Ingredient/Active Moiety

Basis of Strength Strength Ingredient Name

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) **ACETAMINOPHEN** 650 mg

mactive mgreatents	
	Ingredient Name

Strength

HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

POVIDONE K30 (UNII: U725QWY32X)

Inactive Ingredients

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)

HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)

MAGNESIUM STEARATE (UNII: 70097M6I30)

 $\textbf{MICROCRYSTALLINE CELLULOSE} \hspace{0.1cm} \textbf{(UNII: OP1R32D61U)} \\$

STARCH, CORN (UNII: 08232NY3SJ)
STEARIC ACID (UNII: 4ELV7Z65AP)

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			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822- 5091-6	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2024		
2	NDC:11822- 5091-5	225 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2024		
3	NDC:11822- 5091-4	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2024		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	11/01/2024	

Labeler - RITE AID (014578892)

Revised: 1/2025 RITE AID