ACETAMINOPHEN EXTENDED RELEASE- acetaminophen tablet Rite Aid Corporation

Drug Facts

Active ingredient (in each caplet)
Acetaminophen 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
 - 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

D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hydroxyethyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose povidone, pregelatinized starch, sodium lauryl sulfate

Questions or comments?

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

Principal Display Panel

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

8 HR ARTHRITIS PAIN RELIEF

ACETAMINOPHEN

EXTENDED-RELEASE TABLETS 650 mg

PAIN RELIEVER/FEVER REDUCER

for the temporary relief of minor arthritis pain

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 PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY:

RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011 www.riteaid.com

Product Label

Exp. Date: Lot No.:

PLD-A495A FC005883

Orug Facts (continued)

 if you are allergic to acetaminophen or any of the inactive ingredients in this product

Purpose

Active ingredient

Orug Facts

PHARMACY

in each caplet)

Pain reliever/ fever reducer

Acetaminophen 650 mg.

Ask a doctor or pharmacist before use if you are

- pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days
- hese could be signs of a serious condition.

Keep out of reach of children. professional before use.

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see Overdose warning) Directions

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nappily retund your money

SATISFACTION

Ask a doctor before use if you have liver disease.

taking the blood thinning drug warfarin.

hydroxyethyl cellulose, magnesium stearate, maize

starch, microcrystalline cellulose, povidone,

pregelatinized starch, sodium lauryl sulfate

aluminum lake, FD&C yellow #6 aluminum lake, Inactive ingredients D&C yellow #10

■ store between 20-25°C (68-77°F)

Other information

Orug Facts (continued)

Stop use and ask a doctor if

temporarily relieves minor aches and pains due to

minor pain of arthritis

muscular aches

- redness or swelling is present
- new symptoms occur

the common cold

temporarily reduces fever

headache

toothache backache

premenstrual and menstrual cramps

If pregnant or breast-feeding, ask a health

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of

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

Questions or comments?

1-800-222-1222) right away. Quick medical attention do not notice any signs or symptoms

SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

TAMPER EVIDENT: DO NOT USE IF PRINTED

ylenol® 8 HR Arthritis Pain.

do not take more than directed

DISTRIBUTED BY: RITE AID, 30 HUNTER LA<u>NE</u>,

CAMP HILL, PA 17011

www.riteaid.com

WARNINGS AND PRODUCT INFORMATION

KEEP OUTER CARTON FOR COMPLETE

do not take more than 6 caplets in 24 hours

do not use for more than 10 days unless directed

■ under 18 years of age: ask a doctor

Allergy alert: Acetaminophen may cause severe skin sure whether a drug contains acetaminophen, ask If a skin reaction occurs, stop use and seek medical (prescription or nonprescription). If you are not with any other drug containing acetaminophen ■ skin reddening
■ blisters
■ rash reactions. Symptoms may include a doctor or pharmacist help right away. Do not use

this product

3 or more alcoholic drinks every day while using

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

EXTENDED-RELEASE TABLETS 650 mg

Liver warning: This product contains acetaminophen

■ more than 6 caplets in 24 hours, which is the with other drugs containing acetaminophen

maximum daily amount

Severe liver damage may occur if you take:

PAIN RELIEVER/FEVER REDUCER

the temporary of minor arthritis pain

ACTUAL SIZE

*CAPSULE-SHAPED BI-LAYER TABLETS

RITE AID Acetaminophen Extended-Release Tablets

ACETAMINOPHEN EXTENDED RELEASE

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6690
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg		

Inactive Ingredients		
Ingredient Name	Strength	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
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 LAURYL SULFATE (UNII: 368GB5141J)		

Product Characteristics				
Color	white	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	511	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822- 6690-1	1 in 1 BOX	08/12/2019	12/31/2025	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:11822- 6690-5	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/12/2019	12/31/2025	
3	NDC:11822- 6690-0	1 in 1 BOX	08/12/2019	12/31/2025	
3		50 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	ANDA207035	08/12/2019	12/31/2025	

Labeler - Rite Aid Corporation (014578892)

Revised: 2/2023 Rite Aid Corporation