

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

8HR Muscle 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:
- muscular aches
- backache
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- 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

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 and children 12 years of age and over

- 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

children under 12 years

- do not use

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

code # :	
size :	1+3/4 X 1+3/4 X 3+3/8
ref # :	PP180604B
material :	.016 SBS



COATING FREE AREA

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Drug Facts (continued)
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, (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 and children 12 years of age and over
take 2 caplets every 8 hours with water or dissolve and 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
children under 12 years
do not use

Other information
store between 20-25°C (68-77°F)
do not use if foil inner seal is broken or missing

Drug Facts (continued)
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
CONTAINS NO ASPIRIN
This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8 HR Muscle Aches & Pain.

DISTRIBUTED BY:
RITE AID, 30 HUNTER LANE,
CAMP HILL, PA 17011
www.riteaid.com
MADE IN INDIA

SATISFACTION GUARANTEE
If you're not satisfied, we'll happily refund your money.

8 HR MUSCLE PAIN RELIEF ACETAMINOPHEN
EXTENDED-RELEASE TABLETS USP, 650 mg
PAIN RELIEVER/FEVER REDUCER
For up to 8 hours relief of minor muscle aches & pain

50 CAPLETS*
650 MG EACH
OPPOSITE-SHIPPED BI-LAYER TABLETS

8 HR MUSCLE PAIN RELIEF ACETAMINOPHEN
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For up to 8 hours relief of minor muscle aches & pain

50 CAPLETS*
650 MG EACH
OPPOSITE-SHIPPED BI-LAYER TABLETS

Compare to the active ingredient of Tylenol® 8 HR Muscle Aches & Pain

SEE NEW WARNING:
MUSCLE ACHES & PAIN

Important: Read all product information before using. Keep the carton for important information.
Do not use if foil inner seal is broken or missing

Drug Facts
Active ingredient (in each caplet) Purpose
Acetaminophen USP 650 mg... Pain reliever/fever reducer

Uses
temporarily relieves minor aches and pains due to:
muscular aches backache
minor pain of arthritis 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 every day while using this product.
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
skin redness
hives
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

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COATING FREE AREA

Lot
Exp.

code # :		view :	
size :	2+3/32 X 2+3/32 X 4+3/16	material :	.016 SBS
ref # :	PP180604A		



ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-5019
Route of Administration	ORAL		

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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5019-3	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2021	
2	NDC:11822-5019-2	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)