

**PAIN RELIEVER EXTRA STRENGTH- acetaminophen tablet
EQUATE (Wal-Mart Stores, Inc.)**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to
 - headache
 - the common cold
 - backache
 - minor arthritis pain
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- 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 reddening
- blisters
- 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 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 and children 12 years and over
 - take 2 caplets every 6 hours while symptoms last
 - do not take more than 6 caplets in 24 hours
 - do not take 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)

Inactive ingredients

corn starch, croscarmellose sodium*, hypromellose*, lactose monohydrate*, magnesium stearate*, maltodextrin*, medium-chain triglycerides*, mineral oil*, polydextrose*, polyethylene glycol*, polyvinyl alcohol*, povidone, purified water*, sodium starch glycolate*, stearic acid*, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call 1-888-287-1915

Principal Display Panel

Compare to Tylenol® Extra Strength Active Ingredient†

EXTRA STRENGTH

Pain Reliever

Acetaminophen 500 mg

Pain reliever/Fever reducer

CAPLETS

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.

DISTRIBUTED BY:

**Wal-Mart Inc.,
Bentonville, AR 72716**

Product Label

Drug Facts
Active ingredient (in each caplet) Purpose
 Acetaminophen 500 mg.....Pain reliever/fever reducer

Uses ■ temporarily relieves minor aches and pains due to
 ■ headache ■ the common cold ■ backache ■ toothache
 ■ minor pain of arthritis ■ muscular aches ■ premenstrual
 and menstrual cramps ■ temporarily reduces fever

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 4,000 mg of acetaminophen in 24 hours ■ 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 reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away.

Drug Facts (continued under label)

Questions or comments?
 1-888-287-1915

Other information
 ■ store between 20-25°C (68-77°F)

Inactive ingredients corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin, medium-chain triglycerides, mineral oil, polydextrose, polyethylene glycol, polyvinyl alcohol, polydioxane, purified water, sodium starch glycolate, stearic acid, talc, titanium dioxide

Drug Facts (continued)
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 and children 12 years and over ■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours ■ do not take for more than 10 days unless directed by a doctor ■ children under 12 years: do not use

Drug Facts (continued)
 Satisfaction guaranteed - For questions or comments please call 1-888-287-1915.
 DISTRIBUTED BY: Wal-Mart Inc., Bentonville, AR 72716
 † This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.

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 Lot / Exp.:
 PRODUCT OF

PEEL HERE →

EQUATE Extra Strength Pain Reliever

PAIN RELIEVER EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-494
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
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Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0K00R)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	TCL341;AV;0821;P500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-494-24	1 in 1 BOX	05/01/2014	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49035-494-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/01/2014	

Labeler - EQUATE (Wal-Mart Stores, Inc.) (051957769)

