

PAIN RELIEVER EXTRA STRENGTH- acetaminophen tablet

CVS Pharmacy

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

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*, crospovidone*, hypromellose, maltodextrin*, mineral oil*, polydextrose*, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid, talc*, titanium dioxide, triglycerides*

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in TYLENOL® Extra Strength†

Extra Strength

PAIN RELIEVER

CAPLETS

ACETAMINOPHEN

CONTAINS NO ASPIRIN

Pain reliever/Fever reducer

Caplets 500 mg each

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the

registered trademark Tylenol® Extra Strength.

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Product of U.S.A.

Product Label



CVS Extra Strength Pain Relief Caplet

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

KEEP OUTER CARD FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

<p>Drug Facts</p> <p>Active ingredient (in each caplet) Purpose Acetaminophen 500 mg.....Pain reliever/fever reducer</p> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ headache ■ the common cold ■ backache ■ minor pain of arthritis ■ toothache ■ muscular aches ■ premenstrual and menstrual cramps ■ temporarily reduces fever <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> ■ 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 <p>Do not use</p> <ul style="list-style-type: none"> ■ 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 <p>Ask a doctor before use if you have liver disease.</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ new symptoms occur ■ redness or swelling is present <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ do not take more than directed (see Overdose warning) ■ adults and children 12 years and over <ul style="list-style-type: none"> ■ 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 <p>Other information</p> <ul style="list-style-type: none"> ■ store between 20-25°C (68-77°F) <p>Inactive ingredients corn starch*, croscopvidone*, hypromellose, maltodextrin*, mineral oil*, polydextrose*, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid, talc*, titanium dioxide, triglycerides* *contains one or more of these ingredients</p> <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>
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PAIN RELIEVER EXTRA STRENGTH			
acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-158
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
Inactive Ingredients			

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-158-10	1 in 1 BOX	04/30/2014	12/31/2020
1		10 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
OTC MONOGRAPH NOT FINAL	part343	04/30/2014	12/31/2020

Labeler - CVS Pharmacy (062312574)

Revised: 12/2018

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