365 WHOLE FOODS MARKET ACETAMINOPHEN- acetaminophen tablet
Praxis, LLC

Whole Foods Market Acetaminophen Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses
- temporarily relieves minor aches and pains due to:
- the common cold
- headache
- backache
- minor pain of arthritis
- 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 have ever had an allergic reaction to this product or any of its ingredients

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 and over	- take 2 caplets every 6 hours while symptoms last - do not take more than 6 caplets in 24 hours, unless directed by a doctor - do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

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

Inactive ingredients

carnauba wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid

*may contain one or more of these ingredients

Questions or comments?

Principal Display Panel – Non Child Resistant Package

365 WHOLE FOODS MARKET

Extra Strength Acetaminophen 500mg

Pain Reliever/Fever Reducer

Easy to Swallow

Aspirin & Caffeine Free

Compare to the Active Ingredient in Extra Strength Tylenol®

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

ACTUAL SIZE

FOR ADULTS

100 CAPLETS

Drug Facts (continued)

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.

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Questions or comments? 1-800-719-9260

DISTRIBUTED BY: WHOLE FOODS MARKET | 550 BOWIE STREET, AUSTIN, TX 78703 | ©2020 WHOLE FOODS MARKET IP, LP | www.wholefoodsmarket.com

**This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Extra Strength Tylenol®.

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■ skin reddening ■ rash
■ blisters
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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 have ever had an allergic reaction to this product or any of its ingredients

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
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■ 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.

Easy to Swallow
Aspirin & Caffeine Free
Compare to the Active Ingredient in Extra Strength Tylenol®***

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

365
WHOLE FOODS MARKET

NDC 42681-0025-1

Extra Strength

Acetaminophen

500mg
Pain Reliever/Fever Reducer

ACTUAL SIZE
FOR ADULTS

100
CAPLETS

Extra Strength
Acetaminophen
500mg
Pain Reliever/
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DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

100
CAPLETS

ACTUAL SIZE
FOR ADULTS

NDC 42681-0025-1

0 99482 47076 0

48478 K9 C4

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365 WHOLE FOODS MARKET ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59368-216
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	L484
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-216-01	1 in 1 CARTON	08/23/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/23/2020	

Labeler - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-216) , label(59368-216) , pack(59368-216)

Revised: 1/2023

Praxis, LLC