

**ACETAMINOPHEN EASY TABS EXTRA STRENGTH- acetaminophen tablet, coated**

**United Natural Foods, Inc. dba UNFI**

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**ELN - 1092 - 2016-0829**

***Drug Facts***

**Active ingredient (in each tablet)**

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 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 and over	<ul style="list-style-type: none"><li>▪ take 2 tablets every 6 hours while symptoms last</li><li>▪ swallow whole – do not crush, chew, or dissolve</li><li>▪ do not take more than 6 tablets in 24 hours, unless directed by a doctor</li><li>▪ do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>▪ ask a doctor</li></ul>

**Other information**

- store between 20-25°C (68-77°F)
- retain carton for complete product information

## **Inactive ingredients**

acesulfame potassium, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

## **PRINCIPAL DISPLAY PANEL**

EQUALINE®

NDC 41163-192-01

compare to Tylenol® Extra Strength EZ Tabs

active ingredient\*

extra strength

acetaminophen easy tabs

500 mg

- pain reliever/fever reducer • aspirin free
- easy to swallow • sweet coating

100 easy tab tablets



ACETAMINOPHEN EASY TABS EXTRA STRENGTH			
acetaminophen tablet, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-192
<b>Route of Administration</b>	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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	A92
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-192-01	1 in 1 CARTON	11/01/2013	
1		100 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 Drug	M013	11/01/2013	

**Labeler** - United Natural Foods, Inc. dba UNFI (943556183)