

ACETAMINOPHEN- acetaminophen tablet, coated UNFI

1092-ELN-2022-0915

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">▪ take 2 tablets every 6 hours while symptoms last▪ swallow whole – do not crush, chew, or dissolve▪ do not take more than 6 tablets 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	<ul style="list-style-type: none">▪ ask a doctor

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

Questions or comments?

1-855-423-2630

PRINCIPAL DISPLAY PANEL

EQUALINE®

NDC 41163-592-01

compare to Extra Strength Tylenol® Coated Tablets active ingredient*

extra strength

acetaminophen coated tablets

pain reliever/fever reducer

for adults

sweet coated

100 tablets - 500 mg each

actual size



ACETAMINOPHEN

acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-592
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
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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:41163-592-01	1 in 1 CARTON	09/15/2022	
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	09/15/2022	

Labeler - UNFI (943556183)