

PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated
TopCo Associates LLC

TCR - 1170 - 2022-1118

Drug Facts

Active ingredient (in each gelcap)

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 gelcaps every 6 hours while symptoms last• do not take more than 6 gelcaps 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

colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone,

pregelatinized starch, stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 36800-770-02

TopCare® Health

COMPARE TO EXTRA STRENGTH TYLENOL® RAPID RELEASE ACTIVE INGREDIENT†

Extra Strength

Pain Relief

ACETAMINOPHEN 500 mg

PAIN RELIEVER • FEVER REDUCER

For Adults

50 GELCAPS

INK AND COATING FREE FOR LOT AND EXPIRATION STAMPING

0 369661100895 3

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

F1170027CR_R3

The product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Extra Strength Tylenol® Rapid Release Gels.

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Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
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- 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. ▶

Drug Facts (continued)
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
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These could be signs of a serious condition.

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Drug Facts (continued)
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Scan here for more information or call 1-888-423-0139

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TopCare health

COMPARE TO EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS ACTIVE INGREDIENT†

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN 500 mg - PAIN RELIEVER • FEVER REDUCER

For Adults

50 GELCAPS

actual size

COMPARE TO EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS ACTIVE INGREDIENT

actual size

COATING FREE AREA

NDC 36800-770-02

NDC 36800-770-02

PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-770
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	gray (red and light blue ends)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-770-01	1 in 1 CARTON	03/31/2014	08/31/2023
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a		

1		Combination Product		
2	NDC:36800-770-02	1 in 1 CARTON	03/31/2014	
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:36800-770-03	1 in 1 CARTON	03/31/2014	08/31/2022
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:36800-770-05	1 in 1 CARTON	03/31/2014	09/30/2022
4		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:36800-770-12	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2016	03/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/31/2014	

Labeler - TopCo Associates LLC (006935977)

Revised: 12/2024

TopCo Associates LLC