

ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet

Target Corporation

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.

Target 44-519

Active ingredient (in each gelcap)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - the common cold
 - muscular aches
 - backache
 - minor pain of arthritis
 - toothache
 - 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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**
- adults and children 12 years and over
 - 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 take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide

Questions?

Call 1-800-910-6874

Principal Display Panel

NDC 11673-519-20

**Compare to active ingredient in
Extra Strength Tylenol® Rapid Release Gels***

extra strength
**acetaminophen
gelcaps, 500 mg**

pain reliever/fever reducer
quick release

up&up®

225 GELCAPS

225
GELCAPS

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

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels. 50844 REV0417B51920

094 01 0309 R04 ID225450

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Adhesive
Area

STOP PEELING

Drug Facts (continued)

- 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. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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**
- adults and children 12 years and over
- take 2 gelscaps every 6 hours while symptoms last
- do not take more than 6 gelscaps in 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients croscarmellose sodium, D&C red #3, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide

Questions? Call 1-800-910-6874

NDC 11673-519-20

Compare to active ingredient in
Extra Strength Tylenol® Rapid Release Gels*

extra strength
**acetaminophen
gelscaps, 500 mg**

pain reliever/fever reducer
quick release



225 GELCAPS

225
GELCAPS

acetaminophen gelscaps 500 mg acetaminophen gelscaps 500 mg

Drug Facts

Active ingredient (in each gelscap) Acetaminophen 500 mg. Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - headache
 - minor pain of arthritis
 - menstrual 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
- 3 or more other drugs containing acetaminophen every day while using this product

Allergy alert: acetaminophen may cause severe allergic 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.

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No print/No varnish area
Lot no/Exp date

PEEL HERE FOR MORE DRUG FACTS

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-519
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SHELLAC (UNII: 46N107B71O)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	RED, BLUE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-519-12	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2004	
2	NDC:11673-519-15	50 in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2004	
3	NDC:11673-519-20	225 in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/10/2004	

Labeler - Target Corporation (006961700)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(11673-519) , PACK(11673-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11673-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(11673-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(11673-519)

Revised: 8/2019

Target Corporation