

PAIN RELIEVER EXTRA STRENGTH- acetaminophen tablet, coated
Walgreen Company

Walgreens 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
 - 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:

- blisters
- rash
- skin reddening

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

- new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- 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 overdose, get medical help or contact a Poison Control Center 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

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

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 or comments?

1-800-426-9391

Principal Display Panel

Walgreens

Compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels^{††}

NDC 0363-0519-92

Pain

Reliever

ACETAMINOPHEN 500 mg /
PAIN RELIEVER / FEVER REDUCER

Extra Strength

150 GELCAPS

ACTUAL SIZE

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

Walgreens Pharmacist Recommended.

Our pharmacists recommend the
Walgreens brand. We invite you to
compare to national brands.

^{††}This product is not manufactured or
distributed by Johnson & Johnson
Corporation, owner of the registered
trademark Extra Strength Tylenol® Rapid
Release Gels.

DISTRIBUTED BY: **WALGREEN CO.**
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
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<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ if you are allergic to acetaminophen or any of the inactive ingredients in this product ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. 	<p>Ask a doctor before use. If you have liver disease.</p> <hr/> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <hr/> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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 <p>These could be signs of a serious condition.</p> <hr/> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <hr/>	<p>Directions ■ do not take more than directed</p> <ul style="list-style-type: none"> ■ 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 	<p>Other information</p> <ul style="list-style-type: none"> ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ avoid light humidity ■ use by expiration date on package <p>Inactive ingredients crossarmlose 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, polydione, pregelatinized starch, propylene glycol, stearic acid, stearic acid, titanium dioxide</p>	<p>{ Questions or comments? 1-800-426-9391</p>
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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 RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:0363-0519-08	1 in 1 CARTON	05/10/2004	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0363-0519-15	1 in 1 CARTON	05/10/2004	
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0363-0519-12	1 in 1 CARTON	05/10/2004	
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0363-0519-92	150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2004	
5	NDC:0363-0519-19	1 in 1 CARTON	05/10/2004	10/05/2018
5		8 in 1 VIAL; Type 0: Not a Combination Product		
6	NDC:0363-0519-20	1 in 1 CARTON	05/10/2004	04/13/2024
6		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:0363-0519-29	150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2004	07/07/2024
8	NDC:0363-0519-54	375 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2004	05/19/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	M013	05/10/2004	
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Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(0363-0519) , pack(0363-0519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-0519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0363-0519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(0363-0519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0363-0519)