

PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet
L.N.K. International, Inc.

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.

Sound Body 44-519

Active ingredient (in each gelcap)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

- 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.

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

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- 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 or comments?

1-800-426-9391

Principal Display Panel

SOUNDBODY™

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

NDC 50844-951-20

EXTRA STRENGTH

Pain Relief

Acetaminophen 500 mg

Pain Reliever/Fever Reducer

Contains No Aspirin

225 GELCAPS



Actual Size

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 ORG041751920

Manufactured for Big Lots Stores, Inc.
by **LNK INTERNATIONAL, INC.**
60 Arkey Drive, Hauppauge, NY 11788 USA
V#733000 ITEM#022751920

<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have liver disease.</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <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> <p>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.</p>	<p>Directions</p> <ul style="list-style-type: none"> ■ 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 	<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 high humidity ■ use by expiration date on package 	<p>Inactive ingredients crosscarmellose 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, polydione, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide</p>	<p>Questions or comments? 1-800-426-9391</p> <p>STOP PEELING</p>
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 <p>Compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels</p> <p>NDC 50844-951-20</p> <p>EXTRA STRENGTH</p> <p>Pain Relief</p> <p>Acetaminophen 500 mg</p> <p>Pain Reliever/Fever Reducer</p> <p>Contains No Aspirin</p> <p>225 GELCAPS</p> <p>Actual Size</p>	<p>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING</p>	<p>Drug Facts</p> <p>Active ingredient (in each gelscap) Acetaminophen 500 mg Pain reliever/fever reducer</p> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ headache ■ the common cold ■ toothache ■ backache ■ muscular aches ■ minor pain of arthritis ■ premenstrual and menstrual cramps ■ temporarily reduces fever <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> ■ 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 <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</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>*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels. 50844 ORG041751920</p> <p>Manufactured for Big Lots Stores, Inc. by LNK INTERNATIONAL, INC. 60 Arkey Drive, Hauppauge, NY 11788 USA V#733000 ITEM#022751920</p>	 <p>3 50844-95120 5</p> <p>PEEL HERE FOR MORE DRUG FACTS</p>
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Sound Body 44-519

PAIN RELIEF EXTRA STRENGTH
acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-951
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	

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:50844-951-12	1 in 1 CARTON	05/10/2004	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50844-951-15	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2004	
3	NDC:50844-951-20	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 - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-951)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(50844-951) , PACK(50844-951)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-951)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-951)

Revised: 12/2019

L.N.K. International, Inc.