

**PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated
DOLGENCORP, LLC**

Rexall 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
 - muscular aches
 - toothache
 - 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 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
- 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

Principal Display Panel

Since 1903

Rexall®

EXTRA STRENGTH

**Pain Relief
Acetaminophen 500 mg**


- Pain Reliever
- Fever reducer
- Contains no aspirin

120
Gelcaps

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

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120
Gelcaps


UNVARNISHED AREA FOR LOT/EXP. IMPRINT

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

Drug Facts	Purpose
Active ingredient (in each gelcap)	Acetaminophen 500 mg Pain reliever/fever reducer
Uses	temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ headache ■ the common cold ■ backache ■ muscular aches ■ toothache ■ minor pain of arthritis ■ premenstrual and menstrual cramps ■ temporarily reduces fever
Warnings	<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:</p> <ul style="list-style-type: none"> ■ skin reddening ■ blisters ■ rash ■ if a skin reaction occurs, stop use and seek medical help right away.

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PEEL HERE FOR MORE DRUG FACTS

STOP PEELING

Inactive ingredients	crosscarboxymethylcellulose 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
Other information	<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
Directions	<ul style="list-style-type: none"> ■ 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
Drug Facts (continued)	<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> <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.</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>

Rexall 44-519

PAIN RELIEF EXTRA STRENGTH
acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-812
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)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
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:55910-812-32	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2004	
2	NDC:55910-812-08	1 in 1 CARTON	05/10/2004	03/04/2022
2		24 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	05/10/2004	

Labeler - DOLGENCORP, LLC (068331990)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(55910-812) , pack(55910-812)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(55910-812)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(55910-812)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(55910-812)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(55910-812)

Revised: 6/2023

DOLGENCORP, LLC