

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

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**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**

50844 REV0322E51932

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**120**  
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UNVARNISHED AREA FOR LOT/EXP. IMPRINT


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

<b>Drug Facts</b>	
<b>Active ingredient (in each gelcap)</b>	Acetaminophen 500 mg ..... Pain reliever/fever reducer
<b>Uses</b>	temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> <li>■ headache</li> <li>■ the common cold</li> <li>■ backache</li> <li>■ muscular aches</li> <li>■ toothache</li> <li>■ minor pain of arthritis</li> <li>■ premenstrual and menstrual cramps</li> <li>■ temporarily reduces fever</li> </ul>
<b>Warnings</b>	<p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>■ more than 4,000 mg of acetaminophen in 24 hours</li> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>■ skin reddening</li> <li>■ blisters</li> <li>■ rash</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p>

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**PEEL HERE FOR MORE DRUG FACTS**

STOP PEELING

<p><b>Drug Facts (continued)</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ if you are allergic to acetaminophen or any of the inactive ingredients in this product</li> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> </ul> <p><b>Ask a doctor before use if you have liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ pain gets worse or lasts more than 10 days</li> <li>■ fever gets worse or lasts more than 3 days</li> <li>■ new symptoms occur</li> <li>■ redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> 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> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ do not take more than directed</li> <li>■ adults and children 12 years and over</li> <li>■ take 2 gelcaps every 6 hours while symptoms last</li> <li>■ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor</li> <li>■ do not take for more than 10 days unless directed by a doctor</li> <li>■ children under 12 years: ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</li> <li>■ avoid high humidity</li> <li>■ use by expiration date on package</li> </ul> <p><b>Inactive ingredients</b> crosarmallose sodium, D&amp;C red #33, FD&amp;C blue #1, FD&amp;C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide</p>	<p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ if you are allergic to acetaminophen or any of the inactive ingredients in this product</li> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> </ul> <p><b>Ask a doctor before use if you have liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ pain gets worse or lasts more than 10 days</li> <li>■ fever gets worse or lasts more than 3 days</li> <li>■ new symptoms occur</li> <li>■ redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> 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> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ do not take more than directed</li> <li>■ adults and children 12 years and over</li> <li>■ take 2 gelcaps every 6 hours while symptoms last</li> <li>■ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor</li> <li>■ do not take for more than 10 days unless directed by a doctor</li> <li>■ children under 12 years: ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</li> <li>■ avoid high humidity</li> <li>■ use by expiration date on package</li> </ul> <p><b>Inactive ingredients</b> crosarmallose sodium, D&amp;C red #33, FD&amp;C blue #1, FD&amp;C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide</p>
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**Rexall 44-519**

**PAIN RELIEF EXTRA STRENGTH**  
acetaminophen tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-812
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	red, blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	L;5
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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: 6/2024

DOLGENCORP, LLC