

**PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated  
H E B**

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**HEB 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***

- 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
- 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***

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

NDC 37808-195-08

**H-E-B®**

**Extra Strength  
Pain Relief  
Acetaminophen**

500 mg

Pain Reliever/Fever Reducer

**24 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 Tylenol® Extra Strength  
Rapid Release Gels.

50844 REV0322A51908

**MADE WITH PRIDE AND CARE FOR  
H-E-B®, SAN ANTONIO, TX 78204**

**H•E•B®**

**100%  
GUARANTEE  
*promise***

If you aren't completely  
pleased with this product,  
we'll be happy to replace  
it or refund your money.  
You have our word on it.



B-0712-519-08-R  
REV0322A51908

Compare to Tylenol® Extra Strength Rapid Release Gels active ingredient\*  
NDC 37808-195-08

**H-E-B**  
**Extra Strength Pain Relief Acetaminophen 500 mg**  
Pain Reliever/Fever Reducer



**24 GELCAPS**

**Drug Facts** KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

**Purpose**

**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:  
 ■ skin reddening ■ blisters ■ rash  
 If a skin reaction occurs, stop use and seek medical help right away.

**Drug Facts (continued)**

**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  
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**Drug Facts (continued)**  
 ■ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor  
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**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

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® Extra Strength Rapid Release Gels.  
 50844 REV0322A51908



No Print/No Varnish Lot & Expiry Area

**HEB 44-519**

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

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:37808-195 |
| Route of Administration | 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>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)                |                 |
| <b>D&amp;C RED NO. 33</b> (UNII: 9DBA05BB0L)                   |                 |
| <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: 3WJQ0SDW1A)     |                 |
| <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:37808-195-08 | 1 in 1 CARTON   | 05/10/2004                  |                           |
| 1        |                  | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  |                             |                           |
| 2        | NDC:37808-195-12 | 1 in 1 CARTON   | 05/10/2004                  |                           |
| 2        |                  | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                             |                           |
| 3        | NDC:37808-195-20 | 225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/10/2004                  |                           |

**Marketing Information**

| <b>Marketing</b> | <b>Application Number or Monograph</b> | <b>Marketing Start</b> | <b>Marketing End</b> |
|------------------|--|------------------------|----------------------|
|------------------|--|------------------------|----------------------|

| Category           | Citation | Date       | Date |
|--------------------|----------|------------|------|
| OTC Monograph Drug | M013     | 05/10/2004 |      |

**Labeler** - H E B (007924756)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations                      |
|-------------------------|---------|-----------|--|
| LNK International, Inc. |         | 038154464 | manufacture(37808-195) , pack(37808-195) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867837 | manufacture(37808-195) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867894 | manufacture(37808-195) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 868734088 | manufacture(37808-195) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. |         | 967626305 | pack(37808-195)     |

Revised: 9/2023

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