

**PAIN RELIEF EXTRA STRENGTH- acetaminophen capsule, coated**  
**HyVee 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.*

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**Hy-Vee, Inc. Pain Relief Drug Facts**

**Active ingredient (in each caplet)**

Acetaminophen 500 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

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

**Warnings**

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. 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

**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 have ever had an allergic reaction to this product or any of its ingredients

**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. (1-800-222-1222) Quick 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 (see Liver warning)

|  |  |
|--|--|
| adults and children<br>12 years and over | <ul style="list-style-type: none"><li>• take 2 caplets every 6 hours while symptoms last</li><li>• do not take more than 6 caplets in 24 hours, unless directed by a doctor</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul> |
| children under 12 years                  | ask a doctor   |

**Other information**

- store at 20°-25°C (68°-77°F)

**Inactive ingredients**

hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**Questions or comments?**

1-800-719-9260

**Principal Display Panel-Non-CRC**

SEE NEW WARNINGS AND DIRECTIONS

Compare to Extra Strength Tylenol® active ingredient

PAIN RELIEF

EXTRA STRENGTH

Pain Reliever – Fever Reducer

# Acetaminophen

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN {For Non-CRC only}

150 CAPLETS (500 mg EACH)

**GLITEN FREE**

DISTRIBUTED BY HY-VEE, INC.  
5820 WESTOWN PARKWAY  
WEST DES MOINES, IA 50266  
Made in India

SATISFACTION GUARANTEED  
OR PURCHASE PRICE REFUNDED  
FOR INFORMATION CALL  
1-800-289-8343  
www.hy-vee.com

**SEE NEW WARNINGS AND DIRECTIONS**

NDC 42507-017-47

Compare To Extra Strength Tylenol<sup>®</sup> active ingredient

# Hy-Vee<sup>®</sup> PAIN RELIEF

## EXTRA STRENGTH

• Pain Reliever • Fever Reducer  
**Acetaminophen**

**THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN**

**150 CAPLETS (500 mg EACH)**

**DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING**

**Drug Facts**

**Active Ingredient (in each caplet)** Acetaminophen 500 mg

**Purpose** Pain reliever/fever reducer

73647 2H F2

**Uses**

- Temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - backache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - periodontal and menstrual cramps
  - temporary headache

**Warnings**

**Liver warning:** This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- more than 6,000 mg of acetaminophen in 48 hours
- 5 or more alcoholic drinks every day while using this product

**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 have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have liver disease**

**Ask a doctor or pharmacist before use if you are taking any blood thinning drug or vitamin**

**Stop use and ask a doctor if**

- fever persists for more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- itchiness 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 immediately at 1-800-222-1222.**

Quick medical attention is critical for adults as well as for children. If you do not notice any signs or symptoms, ▶

0 75450 07378 2

**FEEL BACK HERE ▶**

**DO NOT USE IF PRINTED SEAL UNDER  
CAP IS BROKEN OR MISSING**

: 73647 2H F2

## Drug Facts

| <b>Active ingredient<br/>(in each caplet)</b> | <b>Purpose</b> |
|---|----------------|
|---|----------------|

|                           |                                 |
|---------------------------|---------------------------------|
| Acetaminophen 500 mg..... | Pain reliever/<br>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. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. 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

### 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 have ever had an allergic reaction to this product or any of its ingredients

**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.

(1-800-222-1222)

Quick medical attention is critical for adults as well as for children even if you do not notice any signs





**Principal Display Panel-CRC**

See New Warnings and Directions

Compare to Extra Strength Tylenol® active ingredient

PAIN RELIEF

EXTRA STRENGTH

Pain Reliever – Fever Reducer

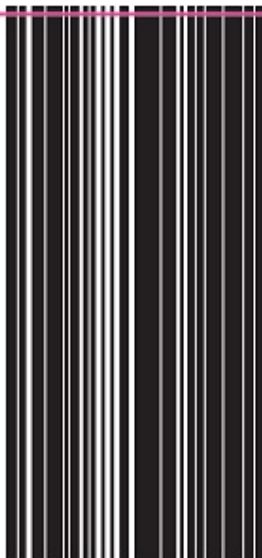
Acetaminophen

Actual Size

100 CAPLETS

500 mg EACH





**Drug Facts**

**Active ingredient** **Purpose**  
**(in each caplet)**

Acetaminophen 500 mg.....Pain reliever/fever reducer

**Uses**

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- 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



NDC 42507-917-78

See New Warnings and Directions

**Tylenol**<sup>®</sup>

Compare to Extra Strength Tylenol<sup>®</sup> active ingredient

**PAIN RELIEF**

**EXTRA STRENGTH**

• Pain Reliever • Fever Reducer  
**Acetaminophen**

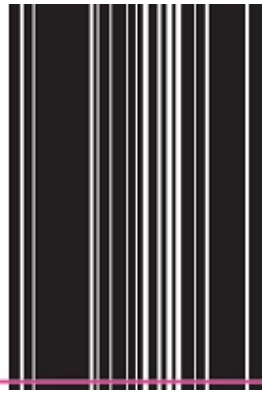
100 CAPLETS 500 mg EACH



Actual Size







## PAIN RELIEF EXTRA STRENGTH

acetaminophen capsule, coated

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:42507-917 |
| 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 |
|---|----------|
| HYPROMELLOSES (UNII: 3NXW29V3WO)        |          |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) |          |
| POVIDONES (UNII: FZ989GH94E)            |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)         |          |

### Product Characteristics

|          |         |              |          |
|----------|---------|--------------|----------|
| Color    | WHITE   | Score        | no score |
| Shape    | CAPSULE | Size         | 16mm     |
| Flavor   |         | Imprint Code | L917     |
| Contains |         |              |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42507-917-62 | 1 in 1 CARTON       |                      |                    |
| 1 |                  | 24 in 1 BOTTLE      |                      |                    |
| 2 | NDC:42507-917-71 | 1 in 1 CARTON       |                      |                    |
| 2 |                  | 50 in 1 BOTTLE      |                      |                    |
| 3 | NDC:42507-917-78 | 1 in 1 CARTON       |                      |                    |
| 3 |                  | 100 in 1 BOTTLE     |                      |                    |

|   |                  |                 |  |  |
|---|------------------|-----------------|--|--|
| 4 | NDC:42507-917-90 | 500 in 1 BOTTLE |  |  |
| 5 | NDC:42507-917-76 | 1 in 1 CARTON   |  |  |
| 5 |                  | 120 in 1 BOTTLE |  |  |
| 6 | NDC:42507-917-47 | 150 in 1 BOTTLE |  |  |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343                                  | 03/14/2011           |                    |

**Labeler** - HyVee Inc (006925671)

**Registrant** - L. Perrigo Company (006013346)

## Establishment

| Name                   | Address | ID/FEI    | Business Operations    |
|------------------------|---------|-----------|------------------------|
| Granules India Limited |         | 918457644 | MANUFACTURE(42507-917) |

## Establishment

| Name               | Address | ID/FEI    | Business Operations                    |
|--------------------|---------|-----------|--|
| L. Perrigo Company |         | 006013346 | REPACK(42507-917) , RELABEL(42507-917) |

## Establishment

| Name               | Address | ID/FEI    | Business Operations |
|--------------------|---------|-----------|---------------------|
| Sixarp LLC, Praxis |         | 016329513 | REPACK(42507-917)   |

Revised: 11/2013

HyVee Inc