

**HEALTHY MAMA SHAKE THAT ACHE- acetaminophen tablet**  
**MATERNAL SCIENCE, LLC**

*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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**Drug Facts**

**Active ingredient (in each caplet)**

Acetaminophen 500 mg

**Purposes**

Pain reliever/fever reducer

**Uses**

- for the temporary relief of minor aches and pains due to:
  - headache
  - muscular aches
  - backache
  - minor pain of arthritis
  - the common cold
  - toothache
  - 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 non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

**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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In the 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 overdose warning)**

**Adults and children 12 years and over:**

- take 2 caplets every 6 hours while symptoms last
- do not take more than 6 caplets 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**

- **Do not use if imprinted safety seal under cap is broken or missing.**
- Store at room temperature

#### **Inactive ingredients**

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid.

#### **Questions?**

If you have any questions or comments, or to report an adverse event, please contact (xxx) xxx-xxxx.

#### **Principal Display Panel**

healthy

mama

SHAKE THAT ACHE!

EXTRA STRENGTH PAIN RELIEVER

aspirin free

100 caplets( 500 mg each)



|  |   |  |
|--|---|--|
| <b>Drug Facts</b>  | <b>Active ingredient (in each caplet)</b><br>acetaminophen 500 mg.....Pain reliever/fever reducer   | <b>Purposes</b>  |
| <b>Uses</b>  | <b>Warnings</b>   | <b>Do not use</b>  |
| <ul style="list-style-type: none"> <li>• for the temporary relief of minor aches and pains due to:               <ul style="list-style-type: none"> <li>• headache</li> <li>• muscular aches</li> <li>• backache</li> <li>• minor pain of arthritis</li> <li>• the common cold</li> <li>• toothache</li> <li>• premenstrual and menstrual cramps</li> </ul> </li> <li>• temporarily reduces fever</li> </ul> | <p><b>Liver warning:</b> 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</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> | <ul style="list-style-type: none"> <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> |
|  | Rev XXXX  | <b>Drug Facts</b> (continued on back)  |

Lot#  
Exp.

|   |
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Rev XX/XX **Drug Facts** (continued on back)  
Do not use if imprinted safety seal under cap is broken or missing

Lot#



Exp.

**Drug Facts** (continued)

• if you are allergic to acetaminophen or any of the inactive ingredients in this product

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**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

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**Other information**

• Store at room temperature

**Inactive ingredients** Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid.

**Questions?** If you have any questions or comments, or to report an adverse event, please contact (XXX) XXX-XXXX.

**HEALTHY MAMA SHAKE THAT ACHE**

acetaminophen tablet

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58 154-100 |
| <b>Route of Administration</b> | ORAL           |                           |                |

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

| <b>Ingredient Name</b> | <b>Strength</b> |
|------------------------|-----------------|
|------------------------|-----------------|

|   |  |
|---|--|
| <b>POVIDONE</b> (UNII: FZ989GH94E)                              |  |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                          |  |
| <b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2) |  |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                          |  |

### Product Characteristics

|                 |                              |                     |          |
|-----------------|------------------------------|---------------------|----------|
| <b>Color</b>    | white                        | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL (capsule shaped tablet) | <b>Size</b>         | 18 mm    |
| <b>Flavor</b>   |                              | <b>Imprint Code</b> | GPI;A5   |
| <b>Contains</b> |                              |                     |          |

### Packaging

| # | Item Code         | Package Description      | Marketing Start Date | Marketing End Date |
|---|-------------------|--------------------------|----------------------|--------------------|
| 1 | NDC:58 154-100-01 | 100 in 1 BOTTLE, PLASTIC |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343                                  | 04/18/2013           |                    |

**Labeler** - MATERNAL SCIENCE, LLC (078722406)

Revised: 4/2013

MATERNAL SCIENCE, LLC