## MAPAP- acetaminophen tablet Aidarex Pharmaceuticals 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 Ingredients (in each tablet)

Acetaminophen 325 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. Severe liver damage may occur if

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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 are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- Pain gets worse or lasts more than 10 days in adults and children
- Pain gets worse or lasts more than 5 days in children under 12 years
- 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 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.

#### Do not use

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#### Ask a doctor before use if the user has

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## Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin

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# Directions Do not take more than directed

| AGE                                   | DOSE  |
|---------------------------------------|---|
| Adults and children 12 years and over | <ul> <li>Take 2 tablets every 4 to 6 hours while symptoms last</li> <li>Do not take more than 12 tablets in 24 hours</li> </ul>   |
| Children 6 to 11 years                | <ul> <li>Take 1 tablet every 4 to 6 hours while symptoms last</li> <li>Do not take more than 5 tablets in 24 hours</li> </ul>   |
| Children under<br>6 years             | Do not use adult Regular Strength products in children under 6 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage. |

#### Other information

• Store at room temperature

#### **Inactive Ingredients**

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid

#### Questions?

To Report Adverse Drug Event call (800) 616-2471 Dist. By MAJOR PHARMACEUTICALS 31778

Enterprise Drive. Livonia, MI 48150

Tamper Evident: Do not use if sealed blister units are broken or damaged.

Reorder No. 251706

## **Principal Display Panel Tablets 325mg**



#### Mapap 325mg tablet

## **MAPAP**

acetaminophen tablet

| Product Information |      |                |                    |                              |
|---------------------|------|----------------|--------------------|------------------------------|
| Product Type        |      | HUMAN OTC DRUG | Item Code (Source) | NDC:33261-142(NDC:0904-1982) |
| Route of Administra | tion | ORAL           |                    |                              |

| Active Ingredient/Active Moiety   |                   |          |  |  |
|---|-------------------|----------|--|--|
| Ingredient Name   | Basis of Strength | Strength |  |  |
| ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN     | 325 mg   |  |  |

| Inactive Ingredients                                     |          |
|--|----------|
| Ingredient Name  | Strength |
| PO VIDO NE (UNII: FZ989 GH94E)                           |          |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                          |          |
| STARCH, CORN (UNII: O8232NY3SJ)                          |          |

| Product Characteristics |                                       |              |          |  |  |
|-------------------------|---------------------------------------|--------------|----------|--|--|
| Color                   | WHITE                                 | Score        | no score |  |  |
| Shape                   | ROUND (round flat faced beveled edge) | Size         | 10 mm    |  |  |
| Flavor                  |                                       | Imprint Code | GPI;A325 |  |  |
| Contains                |                                       |              |          |  |  |

| Packaging |  |  |  |
|-----------|--|--|--|
|           |  |  |  |
|           |  |  |  |

| # | Item Code            | Package Description   | Marketing Start Date | Marketing End<br>Date |
|---|----------------------|---|----------------------|-----------------------|
| 1 | NDC:33261-142-<br>00 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/21/2011           |                       |
| 2 | NDC:33261-142-<br>02 | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/21/2011           |                       |
| 3 | NDC:33261-142-<br>20 | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 04/21/2011           |                       |
| 4 | NDC:33261-142-<br>30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 04/21/2011           |                       |
| 5 | NDC:33261-142-<br>99 | 99 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 0 4/2 1/2 0 11       |                       |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC MONOGRAPH NOT FINAL | part343                                  | 04/21/2011           |                    |  |
|                         |  |                      |                    |  |

## Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 9/2012 Aidarex Pharmaceuticals LLC