

## **ACETAMINOPHEN- acetaminophen tablet**

### **A-S Medication Solutions**

*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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### **Major Pharmaceuticals Acetaminophen Drug Facts**

#### **Active ingredient (in each tablet)**

Acetaminophen 325 mg

#### **Purpose**

Pain reliever/fever reducer

#### **Uses**

- temporarily relieves 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 4,000 mg of acetaminophen in 24 hours
- 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

**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**

- 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 the user has ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if the user**

- has liver disease
- is a child with pain of arthritis

**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 (for adults) or 5 days (for children)
- 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:** 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 overdose warning)**

|                                       |                                                                                                                                                                                                                                           |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| adults and children 12 years and over | <ul style="list-style-type: none"> <li>• take 2 tablets every 4 to 6 hours while symptoms last</li> <li>• do not take more than 10 tablets in 24 hours</li> <li>• do not use for more than 10 days unless directed by a doctor</li> </ul> |
| children 6-11 years                   | <ul style="list-style-type: none"> <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> <li>• do not use for more than 5 days unless directed by a doctor</li> </ul>    |
| children under 6 years                | ask a doctor                                                                                                                                                                                                                              |

**Inactive ingredients**

croscarmellose sodium\*, povidone, pregelatinized starch, stearic acid

\*may contain this ingredient

Questions or comments?

1-800-616-2471

## HOW SUPPLIED

Product: 50090-4238

NDC: 50090-4238-2 100 TABLET in a BOTTLE

NDC: 50090-4238-3 30 TABLET in a BOTTLE

NDC: 50090-4238-4 20 TABLET in a BOTTLE

## Acetaminophen



## ACETAMINOPHEN

acetaminophen tablet

### Product Information

|                         |                |                    |                               |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:50090-4238(NDC:0904-6719) |
| Route of Administration | ORAL           |                    |                               |

### Active Ingredient/Active Moiety

| Ingredient Name                                                    | Basis of Strength | Strength |
|--------------------------------------------------------------------|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN     | 325 mg   |

### Inactive Ingredients

| Ingredient Name                          | Strength |
|------------------------------------------|----------|
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)          |          |

## Product Characteristics

|                 |                      |                     |            |
|-----------------|----------------------|---------------------|------------|
| <b>Color</b>    | WHITE                | <b>Score</b>        | no score   |
| <b>Shape</b>    | ROUND (beveled edge) | <b>Size</b>         | 10mm       |
| <b>Flavor</b>   |                      | <b>Imprint Code</b> | 325MG;L403 |
| <b>Contains</b> |                      |                     |            |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:50090-4238-4 | 20 in 1 BOTTLE; Type 0: Not a Combination Product  | 03/29/2019           |                    |
| 2 | NDC:50090-4238-2 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 03/29/2019           |                    |
| 3 | NDC:50090-4238-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product  | 03/29/2019           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part343                                  | 10/18/2018           |                    |

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

| Name                     | Address | ID/FEI    | Business Operations                      |
|--------------------------|---------|-----------|------------------------------------------|
| A-S Medication Solutions |         | 830016429 | RELABEL(50090-4238) , REPACK(50090-4238) |

Revised: 11/2020

A-S Medication Solutions