

## **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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#### **0220K- Major**

### **Drug Facts**

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

Acetaminophen 325 mg

#### **Purpose**

Pain reliever/ Fever reducer

### **Uses**

Temporarily reduces fever and relieves minor aches and pains due to:

- headache ☐
- muscular aches ☐
- backache ☐
- minor pain of arthritis
- common cold ☐
- toothache ☐
- premenstrual and menstrual cramps

**Liver warning:** This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. 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, which is the maximum daily amount
- 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 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 in adults □
- 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**

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. **This Unit Dose package is not child resistant and is Intended for Institutional Use Only.**

### **Directions**

- **do not take more than directed (see overdose warning)**
- **adults and children 12 years and over:**
  - take 2 tablets every 4 to 6 hours while symptoms last
  - do not take more than 10 tablets in 24 hours, unless directed by a doctor
  - do not use for more than 10 days unless directed by a doctor
- **children 6 years to under 12 years**
  - take 1 tablet every 4 to 6 hours while symptoms last
- do not take more than 5 tablets in 24 hours
- do not use for more than 5 days unless directed by a doctor
- **children under 6 years:** ask a doctor

### **Other information**

store at room temperature

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

### **Questions or comments?**

**(800) 616-2471**

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

Distributed By: **MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

## HOW SUPPLIED

Product: 50090-4273

NDC: 50090-4273-0 1 TABLET in a BLISTER PACK / 30 in a BOX, UNIT-DOSE

## Acetaminophen



## ACETAMINOPHEN

acetaminophen tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4273(NDC:0904-6773)
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
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	CPC;220
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4273-0	30 in 1 BOX, UNIT-DOSE	04/18/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/23/2018	

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

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4273) , REPACK(50090-4273)

Revised: 2/2023

A-S Medication Solutions