

**ACETAMINOPHEN- acetaminophen tablet**  
**Akron Pharma 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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**Acetaminophen 325 mg Tablets**  
**Regular Strength**

**Active ingredient (in each tablet)**

Acetaminophen 325 mg

**Purpose**

Pain Reliever/Fever Reducer

**Uses**

To reduce fever and 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 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 non-prescription). 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**

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

**Ask a doctor or pharmacist before use if your child 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:**

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.

**Directions - do not take more than directed (see overdose warning)**

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adults & 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>

child under 6 years ask a doctor

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### **Other information**

- store at temperature 15° to 30°C (59° to 86°F)

### **Inactive Ingredients:**

colloidal silicon dioxide, microcrystalline cellulose, polacrillin potassium, propylparaben, povidone, stearic acid.

### **Questions or Comments?**

**Call toll-free 1-877-225-6999**

**Manufactured for  
Akron Pharma, Inc.,**

**373 RT US46 W Building E,**

**Suite 117, Fairfield, NJ - 07004**

**Mfg. Lic. No: TN/DRUGS/558/1997**

\* This product is not manufactured or distributed by Johnson and Johnson, consumer inc., distributor of regular Tylenol Tablets.

325mg - Unit Dose

LBH: 73x60x111mm

NDC 71399-8014-1

**Unit Dose**

# Acetaminophen

**REGULAR STRENGTH TABLETS**

## Acetaminophen 325 mg

Pain Reliever / Fever Reducer

**100 Tablets**

\*Compare to the active ingredient in Regular Strength Tylenol® Tablets

NDC 71399-8014-1

**Unit Dose**

Acetaminophen 325 mg  
REGULAR STRENGTH TABLETS

Drug Facts	Purpose
<b>Active ingredient (in each tablet)</b> Acetaminophen 325 mg	Pain reliever/fever reducer
<b>Uses</b> Temporarily reduces fever and relieves minor aches and pains due to: <ul style="list-style-type: none"> <li>■ headache ■ muscular aches ■ backache ■ minor pain of arthritis</li> <li>■ common cold ■ toothache ■ premenstrual and menstrual cramps</li> </ul>	
<b>Warnings</b> <b>Liver warning:</b> 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 the product. <b>Allergy alert:</b> acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash if a skin reaction occurs, stop use and seek medical help right away. <b>Do not use</b> ■ 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. <b>Ask a doctor before use if you have</b> ■ liver disease <b>Ask a doctor or pharmacist before use if you are</b> taking the blood thinning drug warfarin <b>Stop use and ask a doctor if</b> ■ 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. <b>If pregnant or breast-feeding,</b> ask a health professional before use. Keep out of reach of children. <b>Overdose warning:</b> 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. <b>This unit dose package is not child resistant and is intended for institutional use only.</b>	

READ AND KEEP CARTON FOR WARNINGS AND INFORMATION

NDC 71399-8014-1

**Unit Dose**

# Acetaminophen

**REGULAR STRENGTH TABLETS**

## Acetaminophen 325 mg

Pain Reliever / Fever Reducer

**100 Tablets**

NDC 71399-8014-1

**Unit Dose**

Acetaminophen 325 mg  
REGULAR STRENGTH TABLETS

Drug Facts (Continued)	
<b>Directions:</b> ■ do not take more than directed (see overdose warning)	
<b>adults &amp; children 12 years and over</b>	<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>
<b>children 6 years to under 12 years</b>	<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>
<b>child under 6 years</b>	ask a doctor
<b>Other information</b> store at temperature 15° to 30°C (59° to 86°F)	
<b>inactive ingredients</b> colloidal silicon dioxide, microcrystalline cellulose, polyvinylpyrrolidone, propyl paraben, povidone, stearic acid.	
<b>Questions or comments?</b> Call toll-free 1-877-225-6999	

Tamper Evident: Do not use if sealed blister units are broken or damaged.  
 \*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Regular Strength Tylenol® Tablets



N 3 71399 8014 1 8

**Manufactured for:**  
 Akron Pharma, Inc.  
 Fairfield, NJ 07004  
 www.akronpharma.com  
 Rev. 09/22

Lot: \_\_\_\_\_  
 Exp: \_\_\_\_\_

325 mg -100 Tablets



NDC 71399-8024-1

REGULAR STRENGTH

# Acetaminophen

325 MG

TABLETS

ASPIRIN FREE  
PAIN RELIEVER / FEVER REDUCER

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

\*Compare to the active ingredient in Regular Strength Tylenol® Tablets

100 TABLETS

**Drug Facts**

**Active ingredient (in each tablet)**  
Acetaminophen 325 mg ..... Pain reliever/ Fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - backache
  - the common cold
  - 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

**Child-Resistant Packaging**

**Drug Facts (Continued under label)**

Do not use if imprinted safety seal under cap is broken or missing

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Regular Strength

Batch No. :  
Mfg. Date :  
Exp. Date :

PEEL HERE FOR MORE DRUG FACTS

Manufactured for:  
Akrion Pharma, Inc.  
1000 Corporate Center, Suite E  
Suite 117, Fairfield, NJ 07004  
www.akronpharma.com  
18c3122

272230NCCUST04

**Drug Facts (continued)**

**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:** 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.

**Directions** ■ do not take more than directed (see overdose warning)

<b>adults &amp; children 12 years and over</b>	<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>
<b>children 6-11 years</b>	<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>
<b>child under 6 years</b>	ask a doctor

**Other information** store at temperature 15° to 30°C (59° to 86°F)

**Inactive ingredients** colloidal silicon dioxide, microcrystalline cellulose, polyacrylamide potassium, propyl paraben, polyethylene glycol, stearic acid.

**Questions or comments?** Call toll-free 1-877-225-6999

**Mfg. Lic. No.:** TMDRUGS/558/1997

## 325mg -1000 Tablets



NDC 71399-8024-2

REGULAR STRENGTH

# Acetaminophen

325 MG

TABLETS

ASPIRIN FREE  
PAIN RELIEVER/FEVER REDUCER

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

\*Compare to the active ingredient in Regular Strength Tylenol® Tablets

1000 TABLETS

**Drug Facts**

**Active ingredient (in each tablet)**  
Acetaminophen 325 mg ..... Pain reliever/ Fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - backache
  - the common cold
  - 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

**Child-Resistant Packaging**

**Drug Facts (continued)**

**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:** 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.

**Directions** ■ do not take more than directed (see overdose warning)

<b>adults &amp; children 12 years and over</b>	<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>
<b>children 6-11 years</b>	<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>
<b>child under 6 years</b>	ask a doctor

**Other information** store at temperature 15° to 30°C (59° to 86°F)

**Inactive ingredients** colloidal silicon dioxide, microcrystalline cellulose, polyacrylamide potassium, propyl paraben, polyethylene glycol, stearic acid.

**Questions or comments?** Call toll-free 1-877-225-6999

**Mfg. Lic. No.:** TMDRUGS/558/1997

Do not use if imprinted safety seal under cap is broken or missing

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Regular Strength

Batch No. :  
Mfg. Date :  
Exp. Date :

PEEL HERE FOR MORE DRUG FACTS

Manufactured for:  
Akrion Pharma, Inc.  
1000 Corporate Center, Suite E  
Suite 117, Fairfield, NJ 07004  
www.akronpharma.com  
18c3122

# ACETAMINOPHEN

acetaminophen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71399-8014
<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	325 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

## 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>	AP325
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8014-1	100 in 1 PACKAGE	01/15/2021	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH NOT FINAL	part343	01/15/2021	

## ACETAMINOPHEN

acetaminophen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71399-8024
<b>Route of Administration</b>	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### 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>	AP325
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8024-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2021	
2	NDC:71399-8024-2	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	01/15/2021	

**Labeler** - Akron Pharma Inc. (067878881)

**Registrant** - Akron Pharma Inc. (067878881)