

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.

Acetaminophen 325 mg 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)

Do not take more then directed (see overdose warning)

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

child under 6 years

ask a doctor

Other information

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

Inactive Ingredients:

pregelatinized starch, microcrystalline cellulose, povidone, colloidal silicon dioxide, croscarmellose sodium, 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

*This product is not manufactured or distributed by McNeil Consumer Inc., distributor of Regular Strength Tylenol Tablets.

 <p>NDC 71399-2855-5</p> <p>REGULAR STRENGTH</p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet) Acetaminophen 325 mg Pain reliever/fever reducer</p> <p>Purpose</p>	<p>Drug Facts (Continued)</p> <p>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.</p>
<p>Acetaminophen</p> <p>325 MG</p> <p>TABLETS</p>	<p>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 ■ temporarily reduces fever</p>	<p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p>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.</p>
<p>ASPIRIN FREE PAIN RELIEVER / FEVER REDUCER</p>  <p>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</p> <p>*Compare to the active ingredient in Regular Strength Tylenol® Tablets</p> <p>Made in USA </p> <p>50 TABLETS</p>	<p>Warnings</p> <p>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</p> <p>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.</p> <p>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</p>	<p>Directions ■ do not take more than directed (see overdose warning) ■ adults & 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 ■ do not use for more than 10 days unless directed by a doctor ■ children 6-11 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 ■ child under 6 years ask a doctor</p>
	<p>Ask a doctor before use if you have</p> <p>■ has liver disease ■ is a child with pain of arthritis</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p>	<p>Other information store at temperature 15° to 30°C (59° to 86°F)</p> <p>Inactive ingredients pregelatinized starch, microcrystalline cellulose, povidone, colloidal silicon dioxide, croscarmellose sodium, stearic acid</p> <p>Questions or comments? Call toll-free 1877-225-6999</p> <p>Child-Resistant Packaging</p>

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

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Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004
www.akronpharma.com



N 3 71399 2855 3



NDC 71399-8025-1

REGULAR STRENGTH

Acetaminophen**325 MG****TABLETS**ASPIRIN FREE
PAIN RELIEVER / FEVER REDUCERDO NOT USE WITH
OTHER MEDICINES
CONTAINING
ACETAMINOPHEN*Compare to the active ingredient
in Regular Strength Tylenol® Tablets

Made in USA

100 TABLETS

Drug Facts**Active ingredient (in each tablet)**
Acetaminophen 325 mg Pain reliever/fever reducer**Purpose****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 ■ 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
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■ **child under 6 years** ask a doctor**Other information** store at temperature 15° to 30°C (59° to 86°F)**Inactive ingredients** pregelatinized starch, microcrystalline cellulose, povidone, colloidal silicon dioxide, croscarmellose sodium, stearic acid**Questions or comments?** Call toll-free 1-877-225-6999**Child-Resistant Packaging**Do not use if imprinted safety seal under cap is broken or missing.
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Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004
www.akronpharma.com

N 3



NDC 71399-8025-2

REGULAR STRENGTH

Acetaminophen**325 MG****TABLETS**ASPIRIN FREE
PAIN RELIEVER/FEVER REDUCERDO NOT USE WITH
OTHER MEDICINES
CONTAINING
ACETAMINOPHEN*Compare to the active ingredient
in Regular Strength Tylenol® Tablets

Made in USA

1000 TABLETS

Drug Facts**Active ingredient (in each tablet)**
Acetaminophen 325 mg Pain reliever/fever reducer**Purpose****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****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)
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Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004
www.akronpharma.com**ACETAMINOPHEN**

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 71399-2855
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
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	APAP325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-2855-5	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/05/2021	

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-8025
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
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	APAP325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8025-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2021	
2	NDC:71399-8025-2	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/05/2021	

Labeler - Akron Pharma Inc. (067878881)

Revised: 7/2021

Akron Pharma Inc.