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 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)

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 a doctor

child under 6 years ask a doctor

Other information

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

Inactive Ingredients:

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

Questions or Comments?

Call toll-free 1-877-225-6999

Manufactured for
Akron Pharma, Inc.,

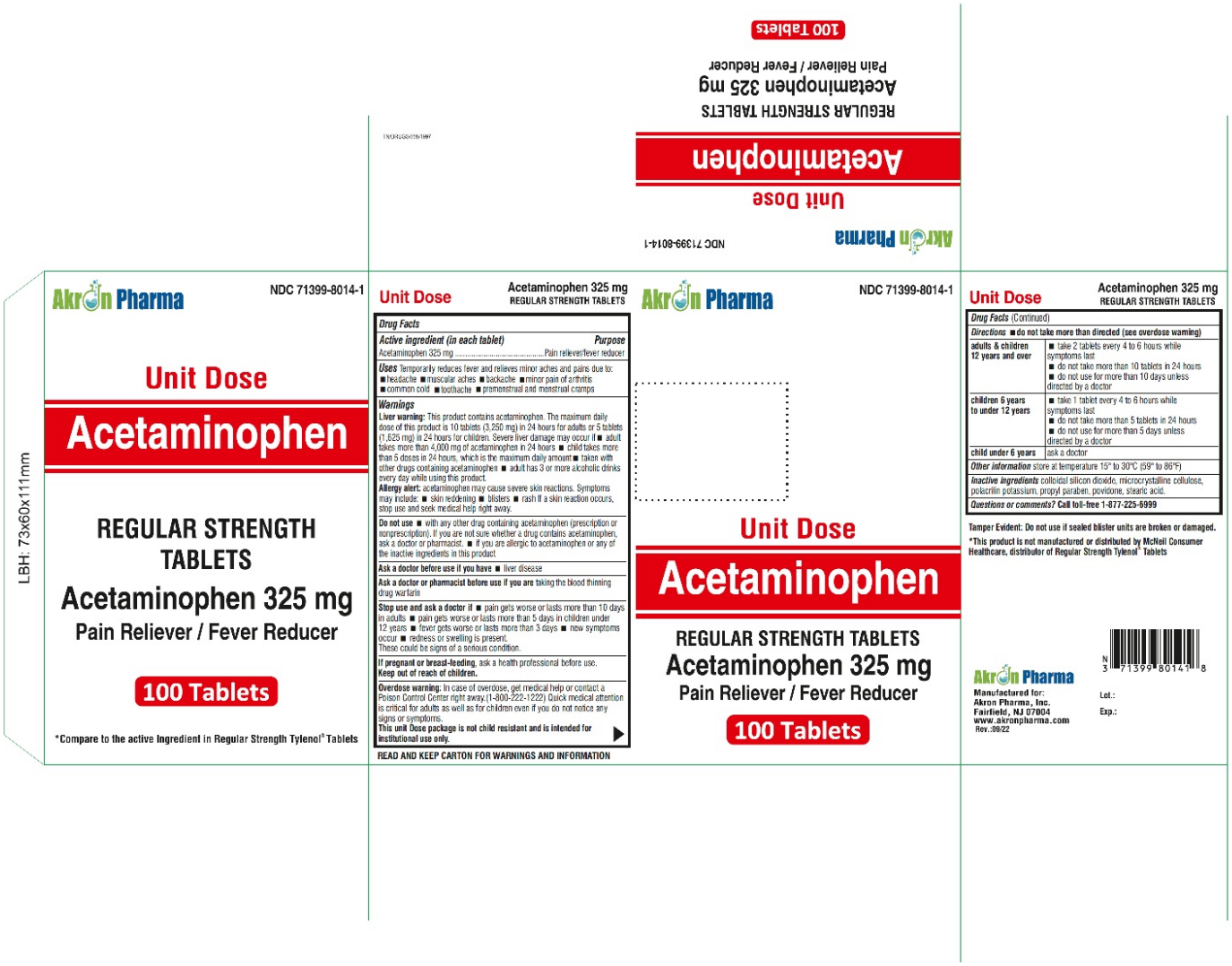
373 RT US46 W Building E,

Suite 117, Fairfeld, NJ - 07004

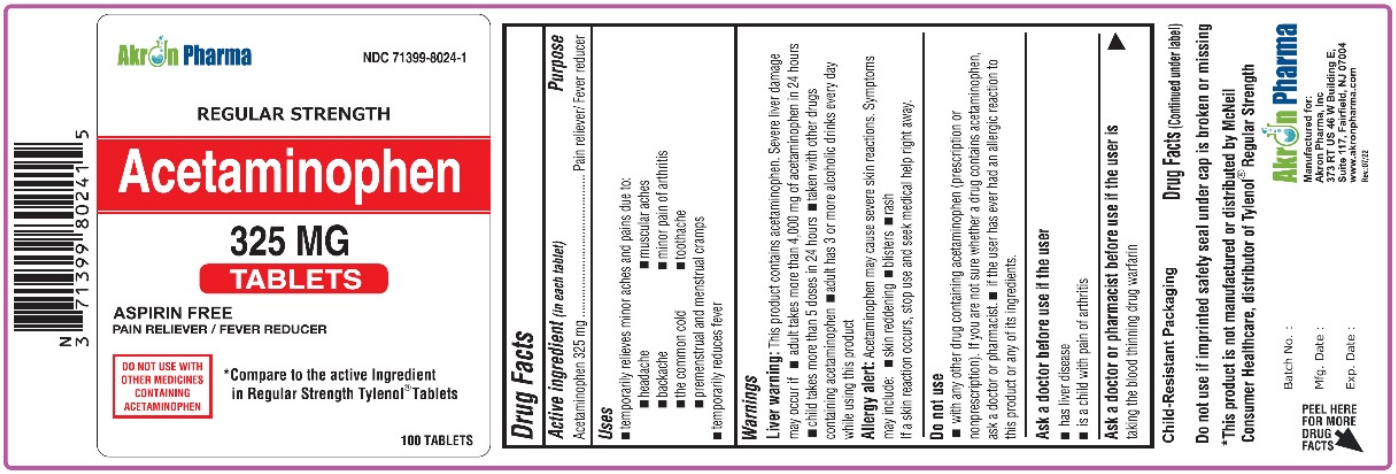
Mfg. Lic. No: TN/DRUGS/558/1997

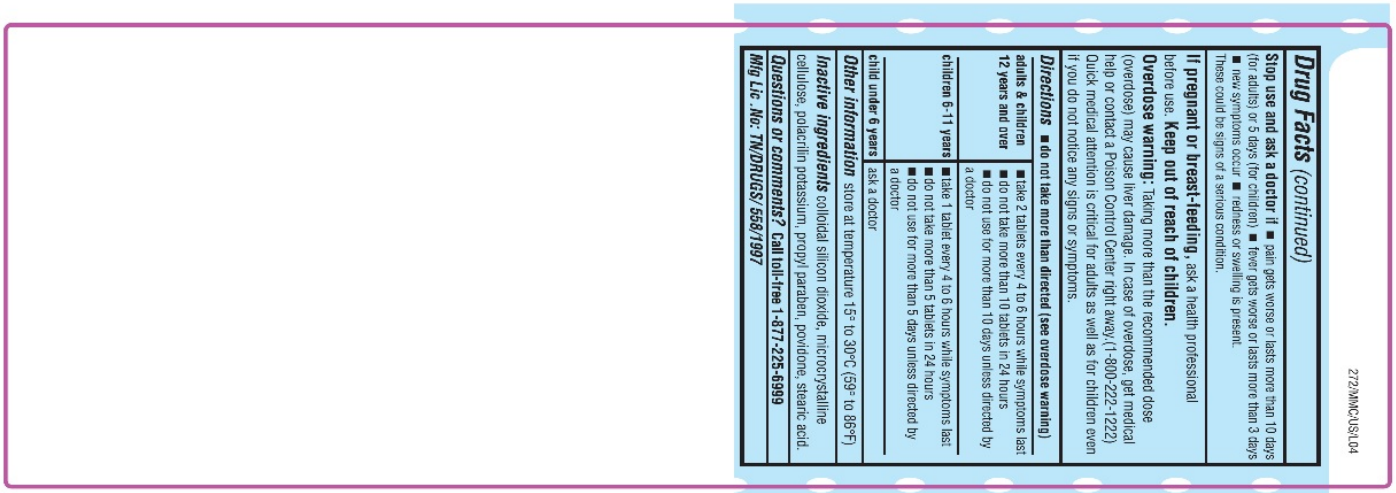
* This product is not manufactured or distributed by Johnson and Johnson, consumer inc., distributor of regular Tylenol Tablets.

325mg - Unit Dose

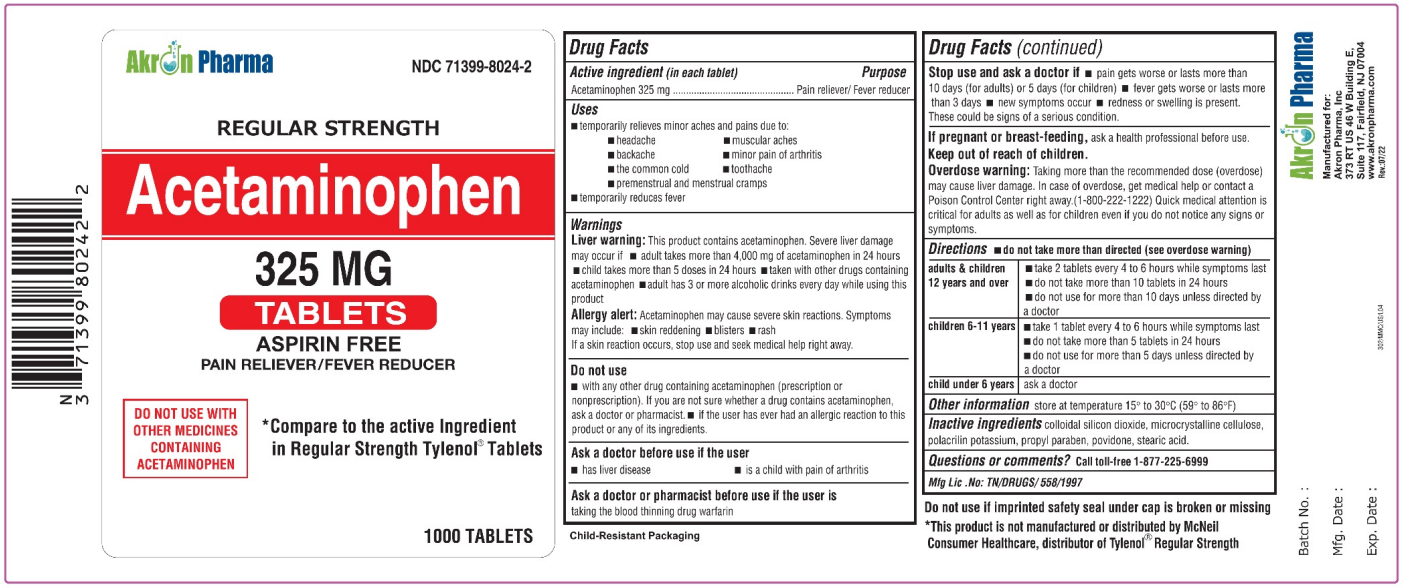


325 mg -100 Tablets





325mg -1000 Tablets



ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-8014
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	AP325
Contains			

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

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

ACETAMINOPHEN

acetaminophen tablet

Product Information

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

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	AP325
Contains			

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)

Revised: 2/2023 Akron Pharma Inc.