

AUROPHEN REGULAR STRENGTH- acetaminophen tablet
Aurohealth LLC

Drug Facts

Active ingredient (in each tablet)

Acetaminophen USP 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 you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has

liver disease

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 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)

Prompt 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">• 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	<ul style="list-style-type: none">• take 1 tablet every 4 to 6 hours while symptoms last• do not take more than 5 tablets in 24

	hours <ul style="list-style-type: none"> do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information

- store at 20° to 25°C (68° to 77°F)
- do not use if carton is opened, or seal under cap is torn or missing.**

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, magnesium stearate, pregelatinized starch, sodium starch glycolate, talc

Questions or comments?

1-855-274-4122

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Distributed by:Aurohealth LLC.
2572 Brunswick Pike, Lawrenceville, NJ 08648

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 325 mg (100 Tablets Bottle)

AUROHEALTH

NDC 58602-754-21

Compare to the active ingredient in Tylenol[®] Regular Strength tablets *

See Warnings Information & Directions

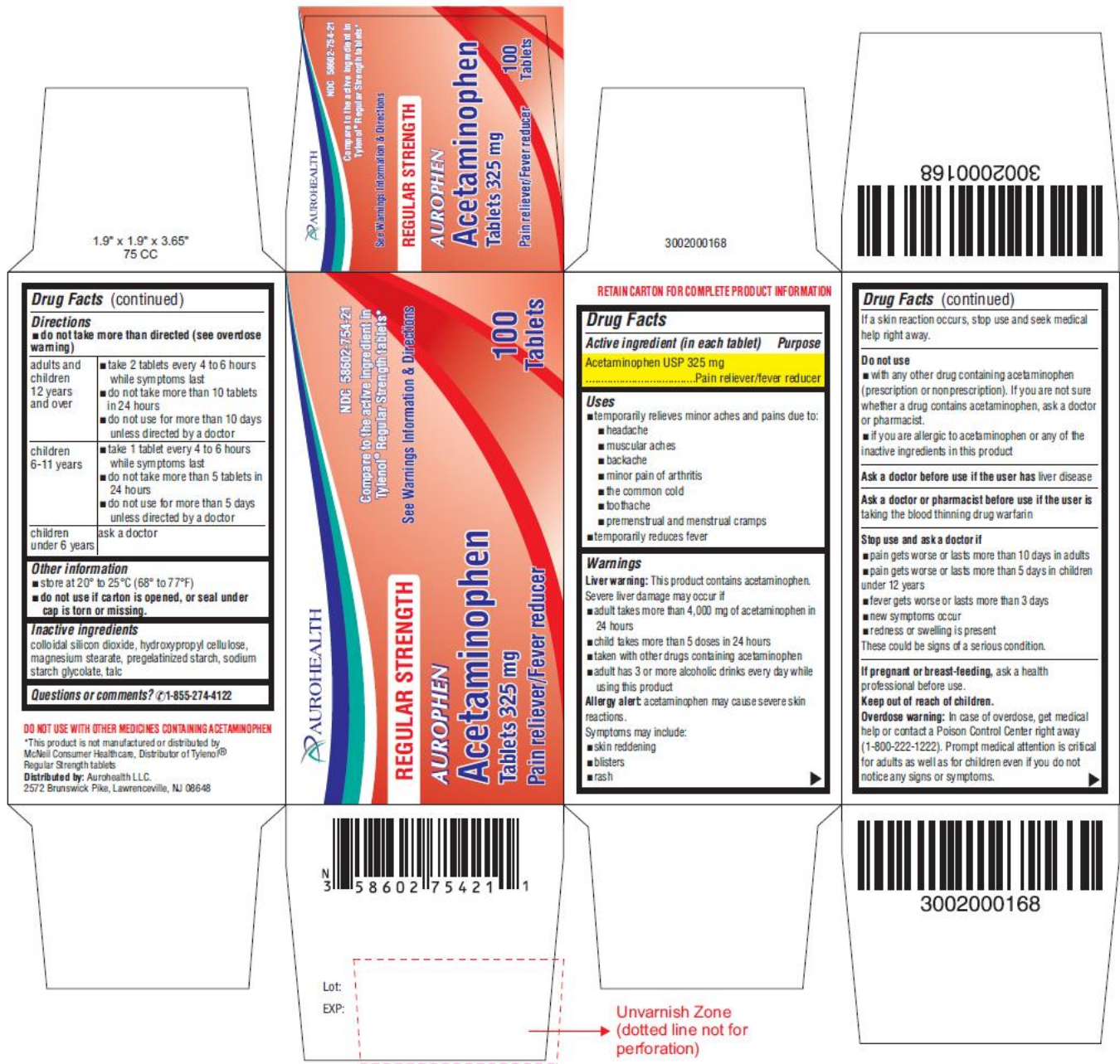
REGULAR STRENGTH

AUROPHEN

Acetaminophen Tablets 325 mg

Pain reliever/Fever reducer

100 Tablets



AUROPHEN REGULAR STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-754
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)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white (White to off White)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	N74
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-754-07	1 in 1 CARTON	02/26/2016	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-754-14	1 in 1 CARTON	02/26/2016	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-754-21	1 in 1 CARTON	02/26/2016	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/26/2016	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	manufacture(58602-754)