ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet
Better Living Brands LLC

Drug Facts

Active ingredient (in each gelcap)

Acetaminophen USP 500 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 you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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
- 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.

Directions

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

adults and children 12 years and over	• take 2 gelcaps every 6 hours while symptoms last • do not take more than 6 gelcaps in 24 hours, unless directed by a doctor • do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F). Avoid high humidity

- **do not use if carton is open. Do not use if printed foil seal under cap is torn or missing**

Inactive ingredients

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, FD&C blue #1, FD&C red #3, FD&C red #40, gelatin, hydroxypropyl cellulose, magnesium stearate, polyethylene glycol, pregelatinized starch (maize), propylene glycol, shellac glaze, sodium starch glycolate, talc and titanium dioxide.

Questions or comments?

Call **1-855-274-4122**

DISTRIBUTED BY:
BETTER LIVING BRANDS LLC
P.O.BOX 99, PLEASANTON,
CA 94566-0009
‡1-888-723-3929

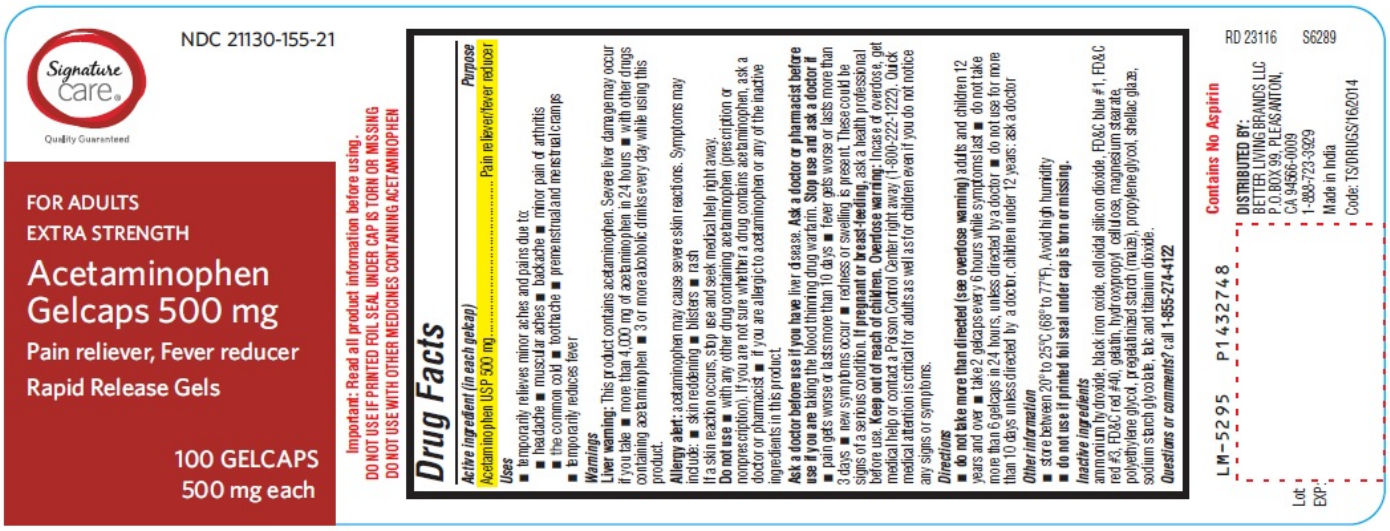
Made in India
Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (100 Gelcaps Container Label)

NDC 21130-155-21
Signature
Care ®
Quality Guaranteed

FOR ADULTS
EXTRA STRENGTH
Acetaminophen
Gelcaps 500 mg
Pain reliever, Fever reducer
Rapid Release Gels

100 GELCAPS
500 mg each



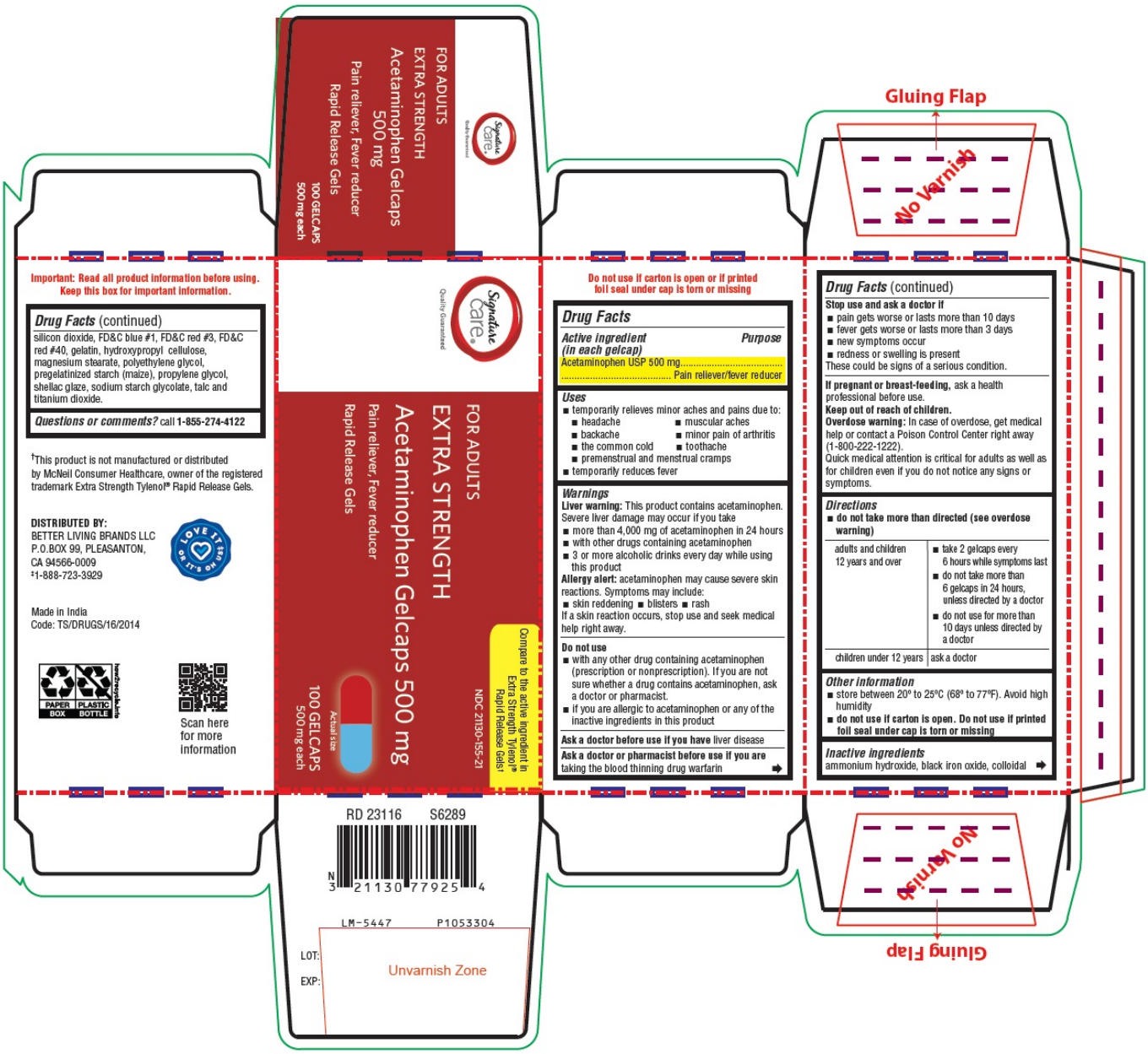
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (100 Gelcaps Container Carton)

Compare to the active ingredient in
Extra Strength Tylenol ®
Rapid Release Gels †
NDC 21130-155-21

Signature
Care ®
Quality Guaranteed

FOR ADULTS
EXTRA STRENGTH
Acetaminophen Gelcaps 500 mg
Pain reliever, Fever reducer
Rapid Release Gels

Actual size
100 GELCAPS
500 mg each



ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-155
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (and Blue with Grey Band)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	J;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-155-21	1 in 1 CARTON	07/14/2023	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-155-35	225 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/14/2023	

Labeler - Better Living Brands LLC (009137209)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations

APL HEALTHCARE LIMITED		650844777	analysis(21130-155) , manufacture(21130-155)