ACETAMINOPHEN- acetaminophen tablet
Granules Pharmaceuticals Inc.

Acetaminophen Tablets 500 mg

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen, USP 500 mg

PURPOSE

Pain reliever/fever reducer

USES

• temporarily relieves minor aches and pains due to:

• the common cold

• headache

• backache

• minor pain of arthritis

• toothache

• muscular aches

• 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 24 hours.

• with other drugs containing acetaminophen

• 3 or more alcoholic drinks everyday 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 drugs 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 other 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 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

Over dose warning: In case of overdose, get medical help or Contact 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 caplets every 6 hours while symptoms last • do not take more than 6 caplets 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 at 20-25°C (68-77°F). See USP Controlled Room Temparature
- avoid high humidity

- See end panel for lot number and expiration date

INACTIVE INGREDIENTS

hydroxyethyl methyl cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

QUESTIONS OR COMMENTS ?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

+All trademarkes are property of their reapective owners.

This product is not affliated with the makers/owners of

Extra Strength Tylenol ® Caplets.

Distributed by:

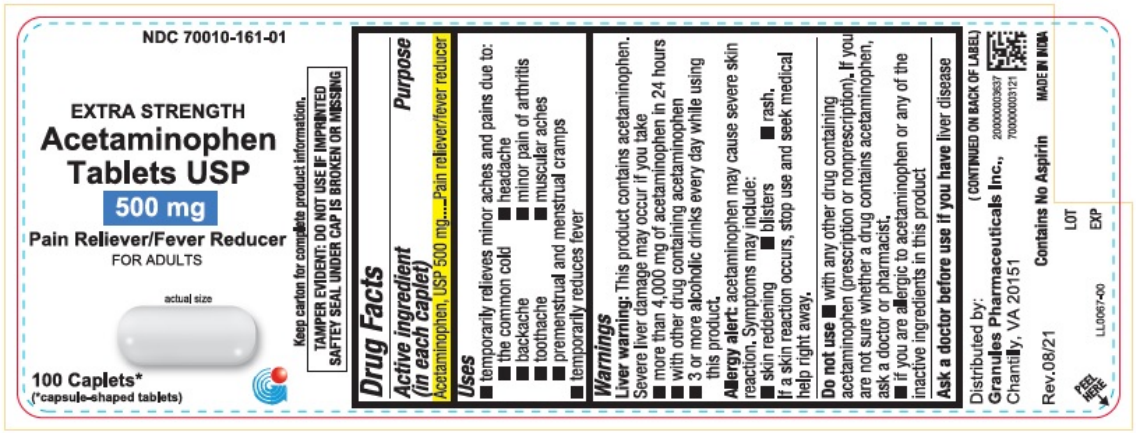
Granules Pharmaceuticals INc.,

Chantilly, VA 20151

MADE IN INDIA

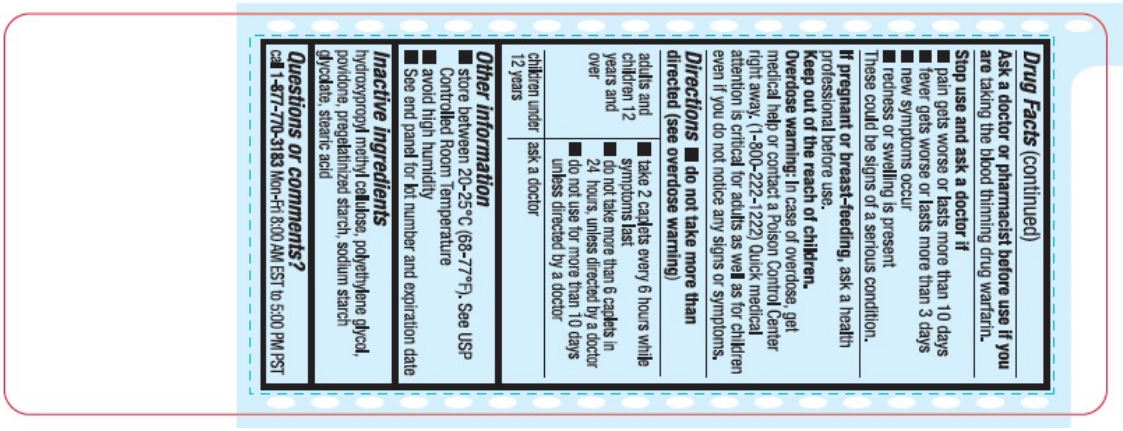
Rev.08/21

PRINCIPAL DISPLAY PANEL



To simulate a printed label, fold along dotted line.

Inside (adhesive side)



Drug Facts (continued)

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 the 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.

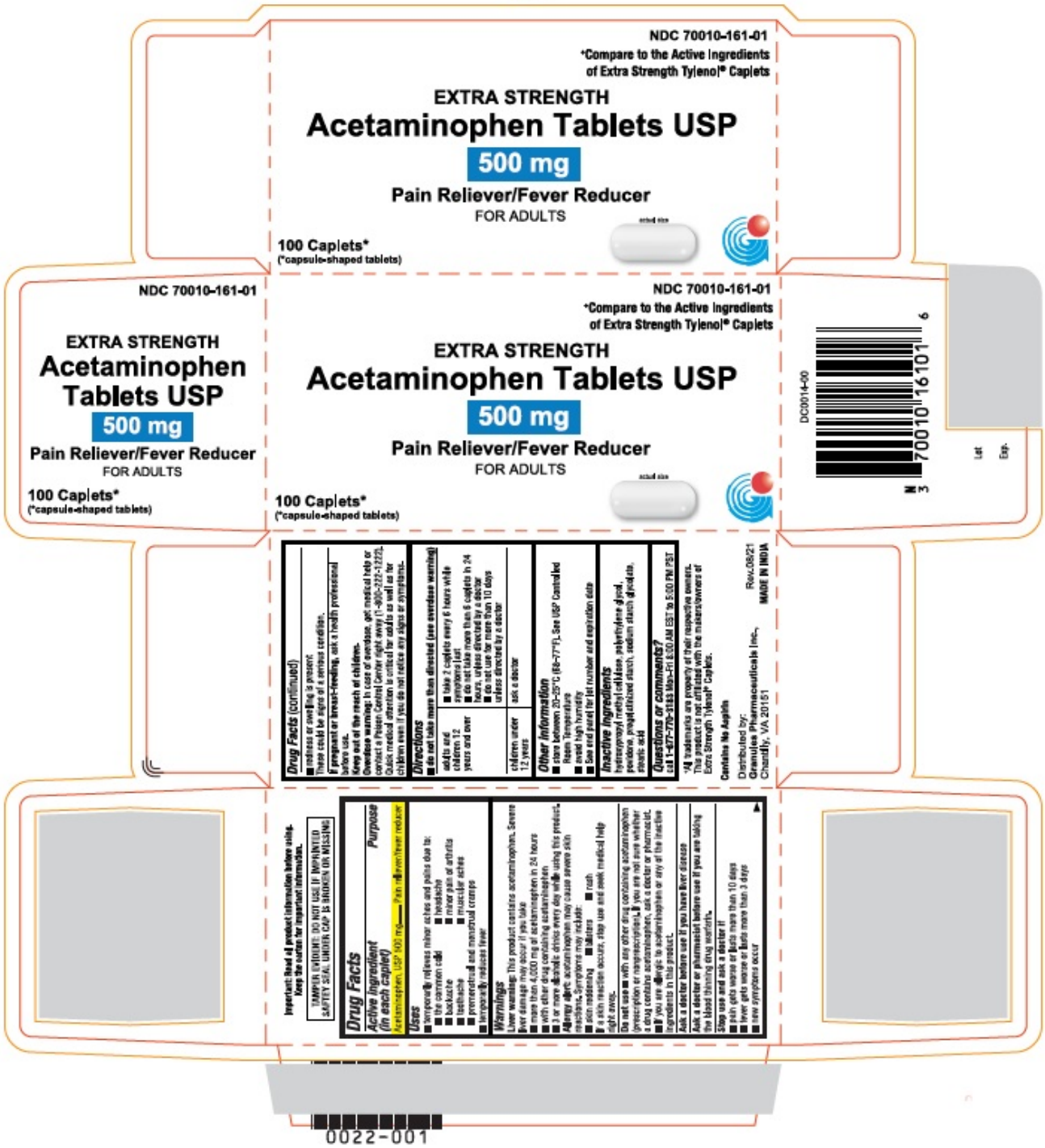
Directions ■ do not take more than directed (see overdose warning)

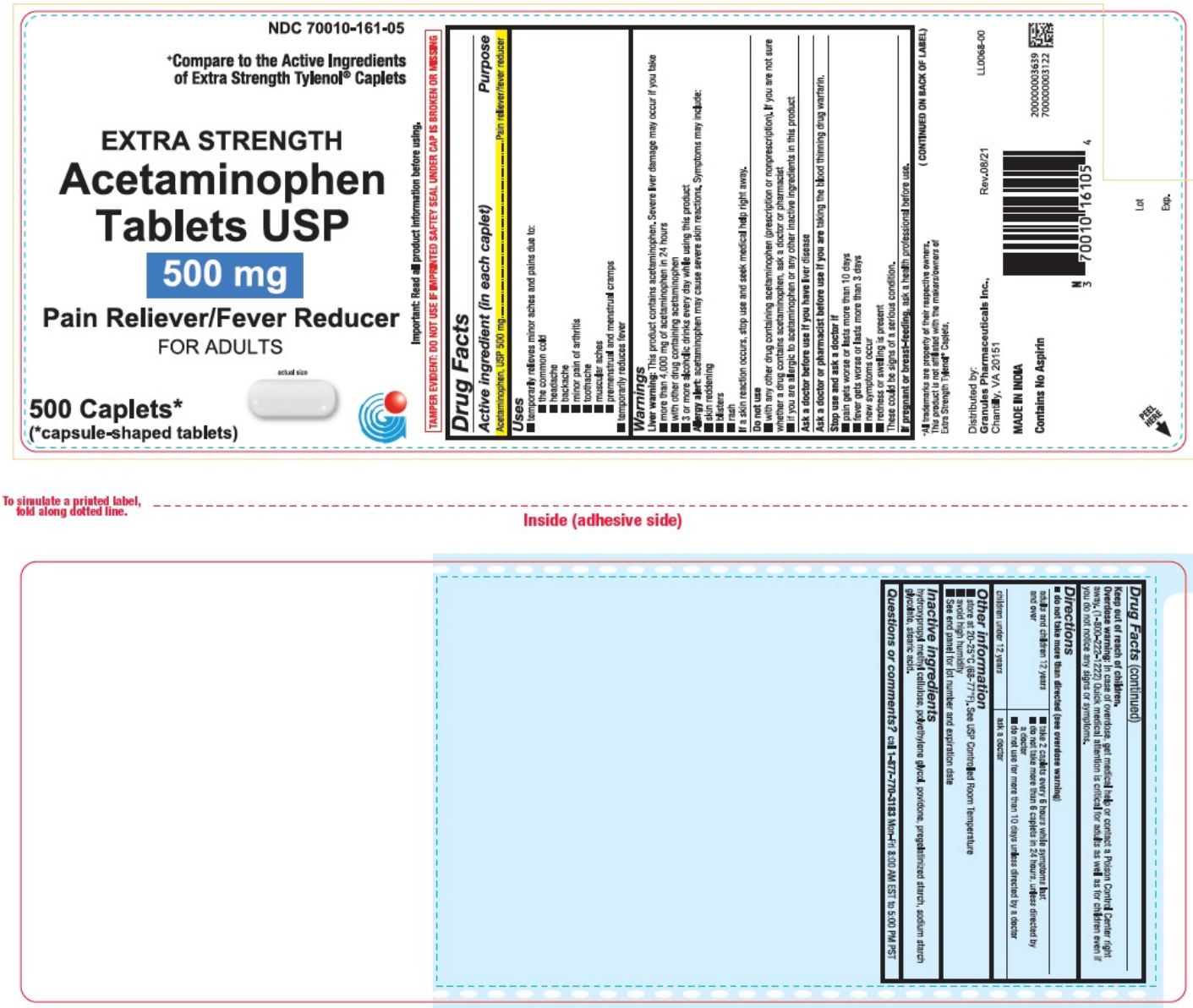
adults and children 12 years and over	■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information
- store between 20-25°C (68-77°F). See USP Controlled Room Temperature
- avoid high humidity
- See end panel for lot number and expiration date

Inactive ingredients
hydroxypropyl methyl cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?
call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST


NDC 70010-161-01
*Compare to the Active Ingredients of Extra Strength Tylenol® Caplets
EXTRA STRENGTH
Acetaminophen Tablets USP
500 mg
Pain Reliever/Fever Reducer
FOR ADULTS
100 Caplets*
(*capsule-shaped tablets)
Drug Facts (continued)
Directions
Other Information
Inactive Ingredients
Questions or comments?
Distributed by:
Gremulus Pharmaceuticals Inc.,
Chantilly, VA 20151
MADE IN INDIA
Drug Facts
Active Ingredient (in each caplet)
Purpose
Uses
Warnings
Keep out of reach of children.
Stop use and ask a doctor if
DC0014-00
Lot
Exp.
0022-001



To simulate a printed label, fold along dotted line.

Inside (adhesive side)

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70010-161
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**
POVIDONE K30 (UNII: U725QWY32X)	

STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white (White to off-White)	**Score**	no score
Shape	CAPSULE (Caplet shape)	**Size**	17mm
Flavor		**Imprint Code**	G551
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70010-161-01	1 in 1 CARTON	02/15/2022	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70010-161-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2022	
3	NDC:70010-161-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		02/15/2022	

Labeler - Granules Pharmaceuticals Inc. (079825711)

Registrant - Granules India Limited (918609236)

Revised: 2/2024 Granules Pharmaceuticals Inc.