ACETAMINOPHEN CAPLETS, 500 MG EXTRA STRENGTH-
acetaminophen tablet
GRAXCELL PHARMACEUTICAL, LLC

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 Caplets, 500 mg, 70795-1200

Active ingredient (in each tablet)

ACETAMINOPHEN 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.
- you have ever had an allergic reaction to this productor any of its ingredients

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.

Do not use

without consulting a physician

Ask a physician before use

if you have a sodium restricted diet due to multiple organ diseases

Stop use and ask a physician

If symptoms of heat cramps continue for more than 24 hours

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

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 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

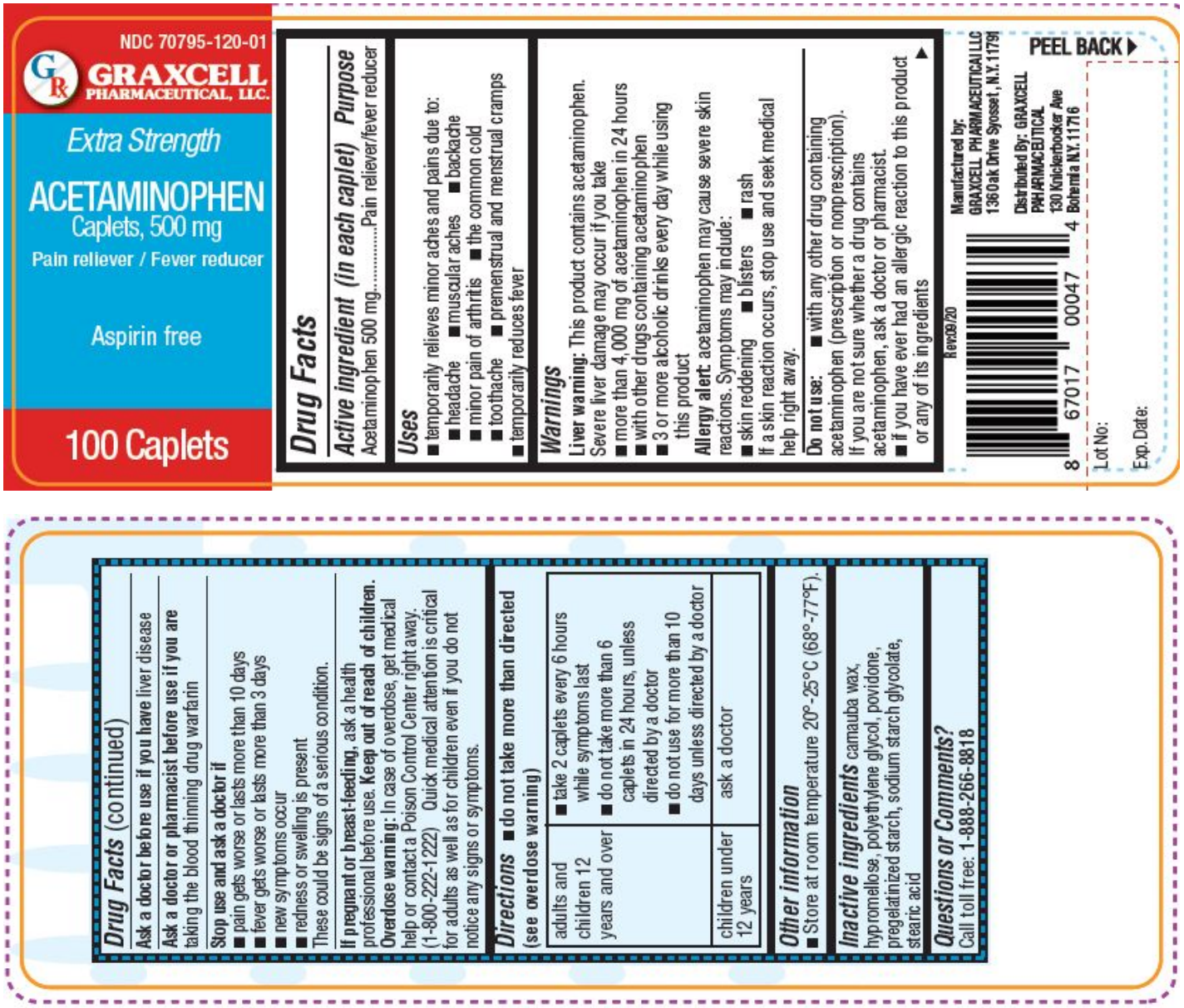
Children under 12 years
- ask a doctor

Other information

- Store at room temperature 20°-25°C (68°-77°F).

INACTIVE INGREDIENTS

carnauba wax, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid



ACETAMINOPHEN CAPLETS, 500 MG EXTRA STRENGTH

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70795-1200
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	500
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70795-1200-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2020	
2	NDC:70795-1200-2	200 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/16/2020	

Labeler - GRAXCELL PHARMACEUTICAL, LLC (056556923)

Revised: 12/2021 GRAXCELL PHARMACEUTICAL, LLC