ACETAMINOPHEN- acetaminophen tablet
Granules USA, Inc

EXTRA STRENGTH
Pain Relief
Acetaminophen Gelcaps USP, 500 mg
Pain reliever; Fever reducer
Rapid Release
Aspirin free

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

■ toothache

■ he common cold

■ premenstrual and menstrual cramps

■ temporarily reduces fever

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 have ever had an allergic reaction to this product or 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.

Keep out of the reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

overdose warning

In case of accidental overdose, get medical help or contact a Poison Control Centerright 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 take 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 Temperature

■ avoid high humidity

■ see end panel for lot number and expiration date

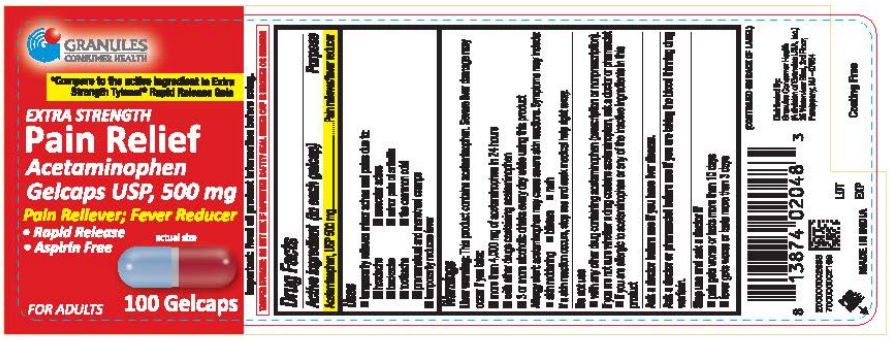
Inactive ingredients

ammonium hydroxide, black iron oxide, black iron oxide irradiated, colloidal silicon dioxide, croscarmellose sodium, gelatin, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hypromellose, iron oxide red, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, yellow iron oxide.

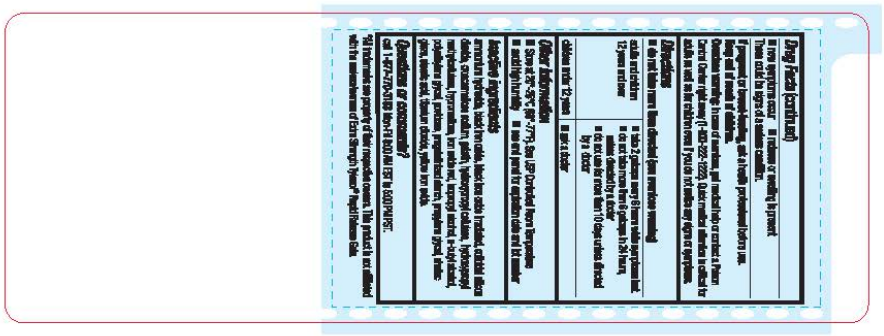
Questions or comments?

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

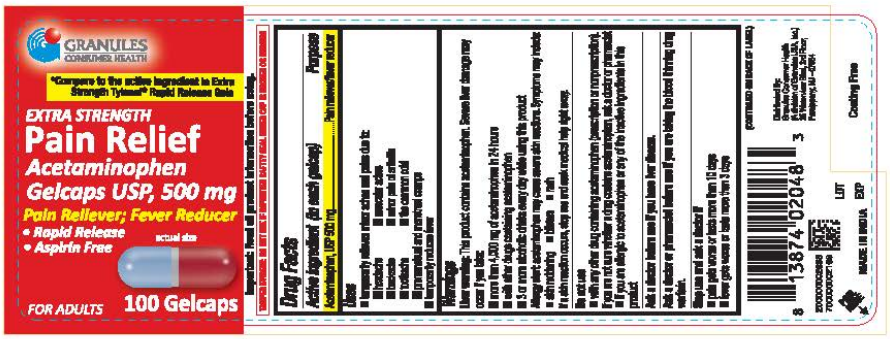
Acetaminophen, USP 500 mg Rapid Release Gelcaps



Inside (adhesive side)



PDP



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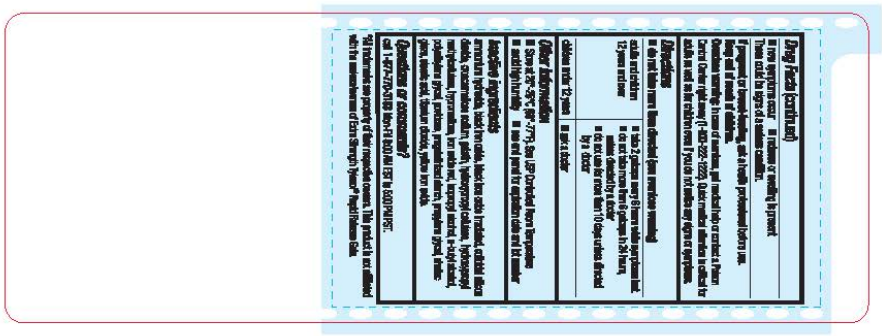

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69848-008
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**
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
AMMONIA (UNII: 5138Q19F1X)	
GELATIN (UNII: 2G86QN327L)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	gray (Encapsulated with red opaque and blue gray opaque hard gelatin shells)	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	G1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-008-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2020	

Labeler - Granules USA, Inc (137098864)

Revised: 12/2023 Granules USA, Inc