ACETAMINOPHEN- acetaminophen capsule
FREDS, INC

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.

EXTRA STRENGTH
PAIN RELIEVER
ACETAMINOPHEN, USP 500 mg
Pain Reliever/Fever Reducer

Active ingredient

(in each Caplet)
Acetaminophen, USP 500 mg

Purpose

Pain reliever/fever reducer

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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

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 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 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
■ See end panel for lot number and expiration date

Inactive ingredients

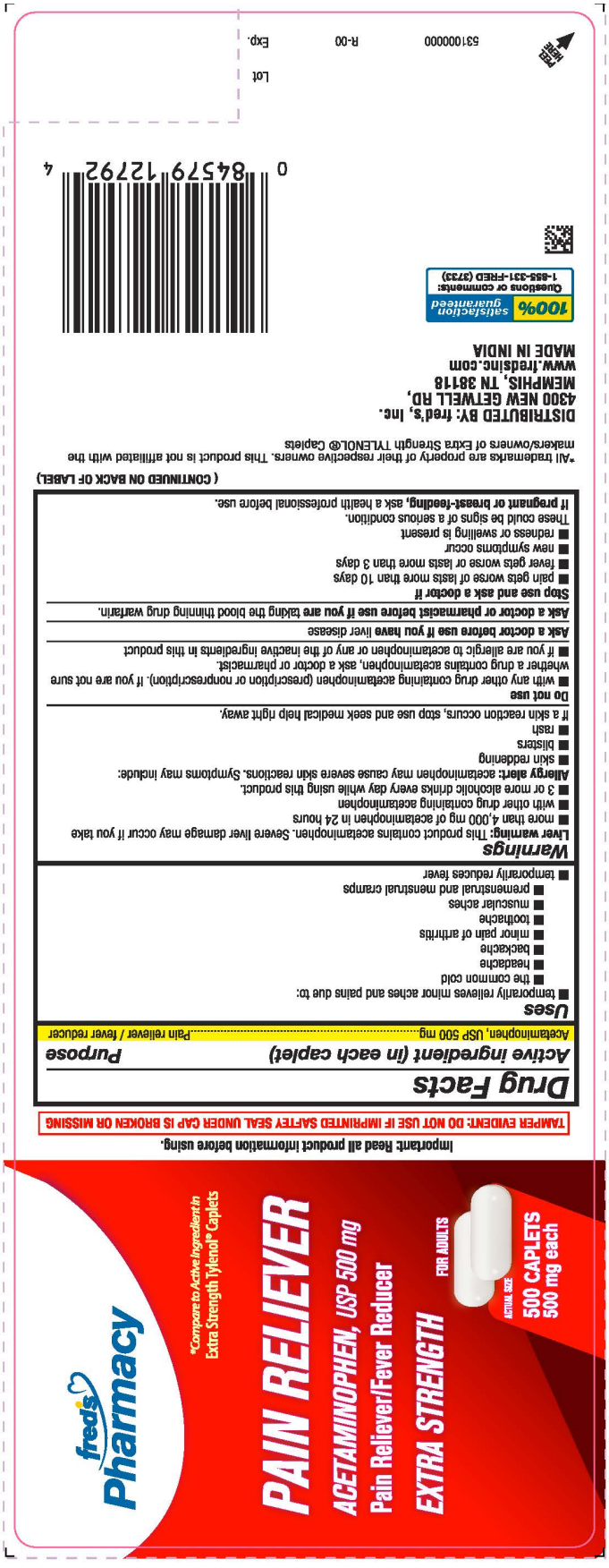
hydroxypropyl methyl cellulose, pregelatinized starch, povidone k-30, polyethylene glycol, stearic acid, sodium starch glycolate

Questions or comments?

call **1-877-770-3183** Mon-Fri 9:00 AM to 4:30 PM EST

EXTRA STRENGTH
PAIN RELIEVER
ACETAMINOPHEN, USP 500 mg
Pain Reliever/Fever Reducer
100 CAPLETS**
**** Capsule-Shaped Tablets**
500 mg each

EXTRA STRENGTH
PAIN RELIEVER
ACETAMINOPHEN, USP 500 mg
Pain Reliever/Fever Reducer
500 CAPLETS
500 mg each



ACETAMINOPHEN

acetaminophen capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-989
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**
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	G551
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55315-989-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	
2	NDC:55315-989-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/17/2017	

Labeler - FREDS, INC (005866116)

Revised: 7/2017 FREDS, INC