ACETAMINOPHEN- acetaminophen tablet, coated
Bonita Pharmaceuticals 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.

Extra Strength Acetaminophen 500mg Caplets

Active Ingredient

(in each caplet)

Acetaminophen 500mg

Purposes

Pain reliever/Fever reducer

Uses

For the temporary relief of 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. The maximum daily dose of this product is 6 caplets (3,000mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 pressent

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:

Taking more than the recommended dose (overdose) may cause liver damage. 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 take for more than 10 days unless directed by a doctor

Children under 12years: ask a doctor

Other Information

- **Do not use if imprinted safety seal under cap is broken or missing**
- Store at room temperature

Inactive Ingredients

- Povidone
- Pregelatinized Starch
- Sodium Starch Glycolate
- Stearic Acid

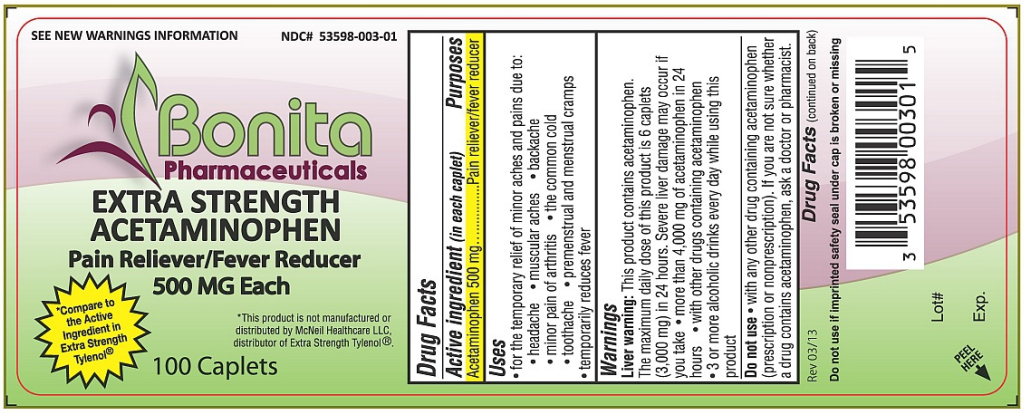
Questions?

If you have any questions or comments, or to report an adverse event, please contact (855) 729-7200.

PRINCIPAL DISPLAY PANEL

Image 1 : Extra Strength Acetaminophen 500mg, 1000ct caplets

Front Top



FOLD PROOF ALONG DOTTED LINE

to simulate an actual printed label layout

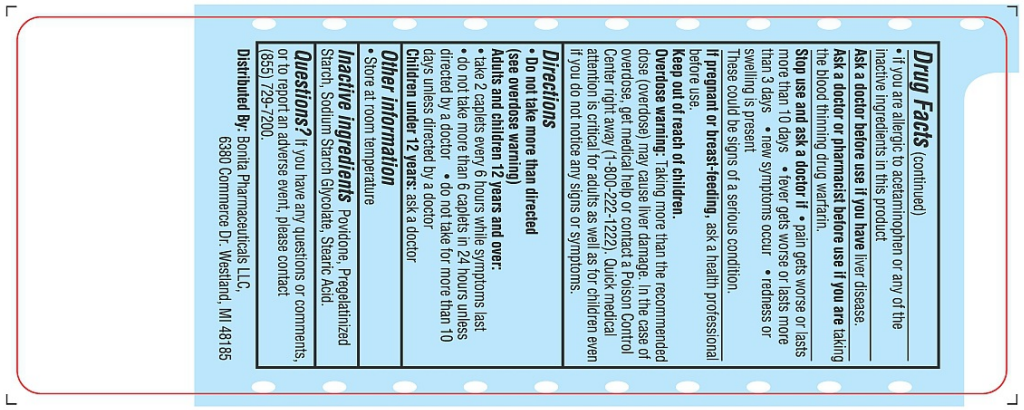


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Image 2 : Extra Strength Acetaminophen 500mg, 100ct caplets

ACETAMINOPHEN
acetaminophen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53598-003
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 (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL ((Capsule Shaped Tablets))	**Size**	17mm
Flavor		**Imprint Code**	GPI;A5
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53598-003-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:53598-003-10	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/02/2013	

Labeler - Bonita Pharmaceuticals LLC (004219442)

Registrant - Bonita Pharmaceuticals LLC (004219442)

Establishment

Name	Address	ID/FEI	Business Operations
Bonita Pharmaceuticals LLC		004219442	label(53598-003)