ACETAMINOPHEN - acetaminophen tablet
Keltman Pharmaceuticals 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.

Acetaminophen Tablet

*Compared to the active ingredient in Extra-Strength Tylenol® Tablets

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Acetaminophen 500 mg

PURPOSES

Pain Reliever/Fever Reducer

Keep Out of Reach of Children

Keep out of reach of children

USES

- temporarily relieves minor aches and pains
- temporarily relieves reduces fever

WARNINGS

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 tablets in 24 hours, which is the maximum daily amount
- 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.

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 reach of children.

OVERDOSAGE

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. 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

Age	Dose
Adults and Children 12 years and over	Take 1-2 tablets every 4-6 hours, as needed. Do not take more than 8 tablets in 24 hours.
Children under 12 years	Do not use.

OTHER INFORMATION

TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.

- store at 20°-25°C (68°-77°F)
- for institutional use only

INACTIVE INGREDIETNS:

povidone, sodium starch glycolate, starch, stearic acid. May also contain: crospovidone, methylparaben and propylparaben

Distributor Information:

*This product is not manufactured or distributed by the owner of the registered trademark TYLENOL®.

Distributed by: GERI-CARE PHARMACEUTICALS CORP. 1650 63rd St., Brooklyn, New York 11204

This Product was Repackaged By Sandhills Packaging For:

Keltman Pharmaceuticals Inc.
1 Lakeland Square, Suite A
Flowood, MS 39232
United States

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68387-214(NDC:57896-201)
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, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	M2A4;57344
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68387-214-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	01/01/2011	

Labeler - Keltman Pharmaceuticals Inc. (362861077)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals Inc.		362861077	repack, relabel

Revised: 3/2011 Keltman Pharmaceuticals Inc.