ACETAMINOPHEN - acetaminophen tablet
Velocity Pharma

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 Extra Strength 500 mg

Active Ingredient

(in each tablet)

Acetaminophen 500mg

Purpose

pain reliever/fever reducer

Uses

- temporarily reduces fever

Warnings

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

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product

do not use

- with any other drug containing acetaminophen (prescription or not prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- If you have ever had an allergic reaction to acetaminophen or any of the inactive ingredients in this product.

ask a doctor before use if you have liver disease

ask your 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
- redness or swelling is present
- new symptoms appear
  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 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 of this product in 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor
  children under 12 years:
- Ask a doctor

Other Information

- Store at a controlled temperature between 62° and 77 °F)

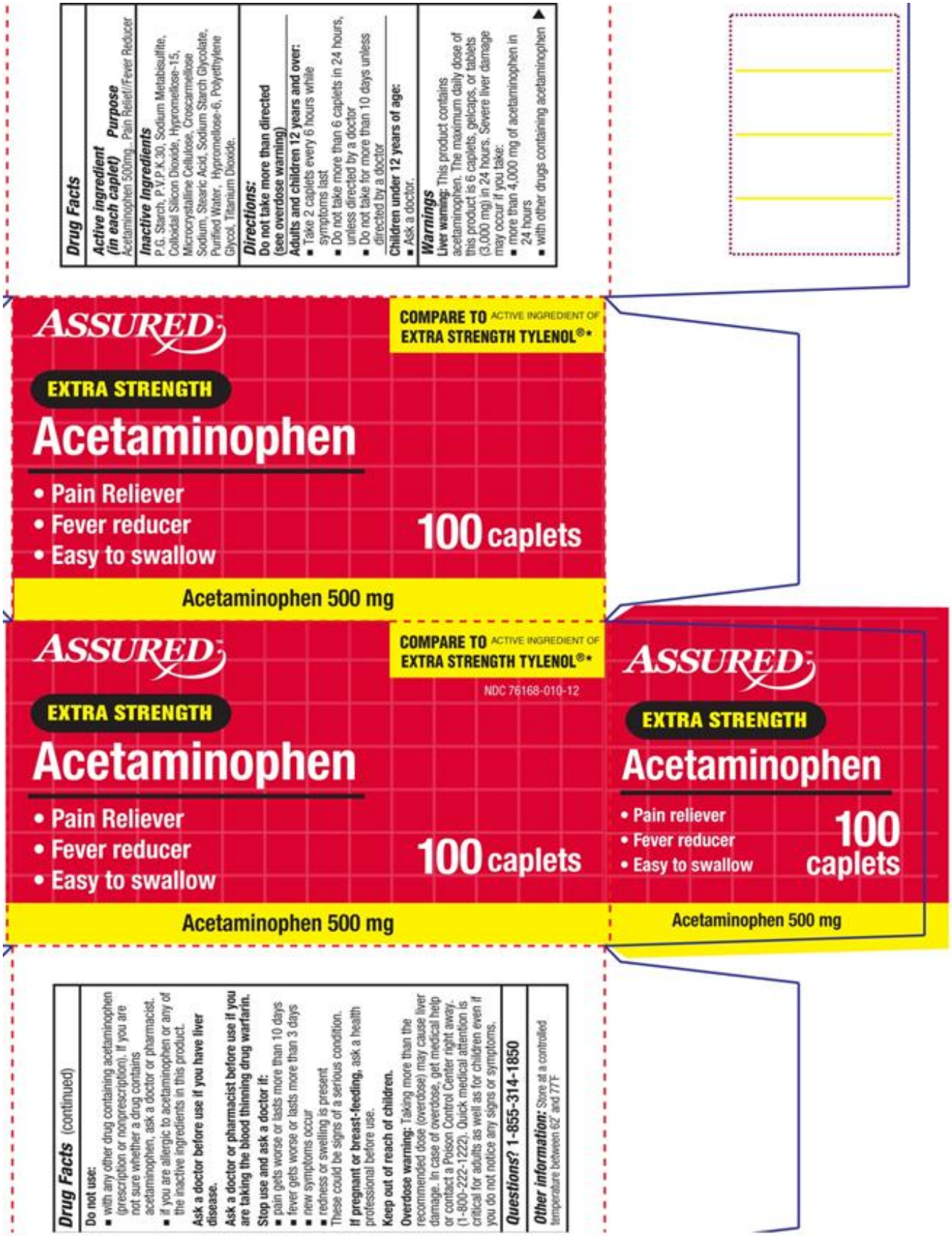
Inactive Ingredients

P.G Starch, P.V.P.K.30, sodium metabisulfite, colloidal silicon dioxide, Hypromellose-15, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Sodium Starch Glycolate, Hypromellose-6, Polyethylene Glycol, Titanium Dioxide.

Questions or Comments

Questions? 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



NDC: 76168-010 -12 100 COUNT

ACETAMINOPHEN
acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-010
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**
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76168-010-12	100 in 1 BOTTLE		
1		1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/05/2012	

Labeler - Velocity Pharma (962198409)