APAP- acetaminophen tablet
Richmond 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 USP 500 mg

Active Ingredient

(in each caplet)

Acetaminophen 500 mg

Purpose

Pain Reliever / Fever Reducer

Uses

temporarily relieves 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 (3,000 mg) in 24 hours. 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

do not use

- with any other drug containing acetaminophen (prescription or non prescription). 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 the 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
- redness or swelling is present
- new symptoms occur

- 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. 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 over dose warning) adults & 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 12 years : ask a doctor**

Other Information

- store at 15-30 °C (59-86 °F)

Inactive Ingredients

polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

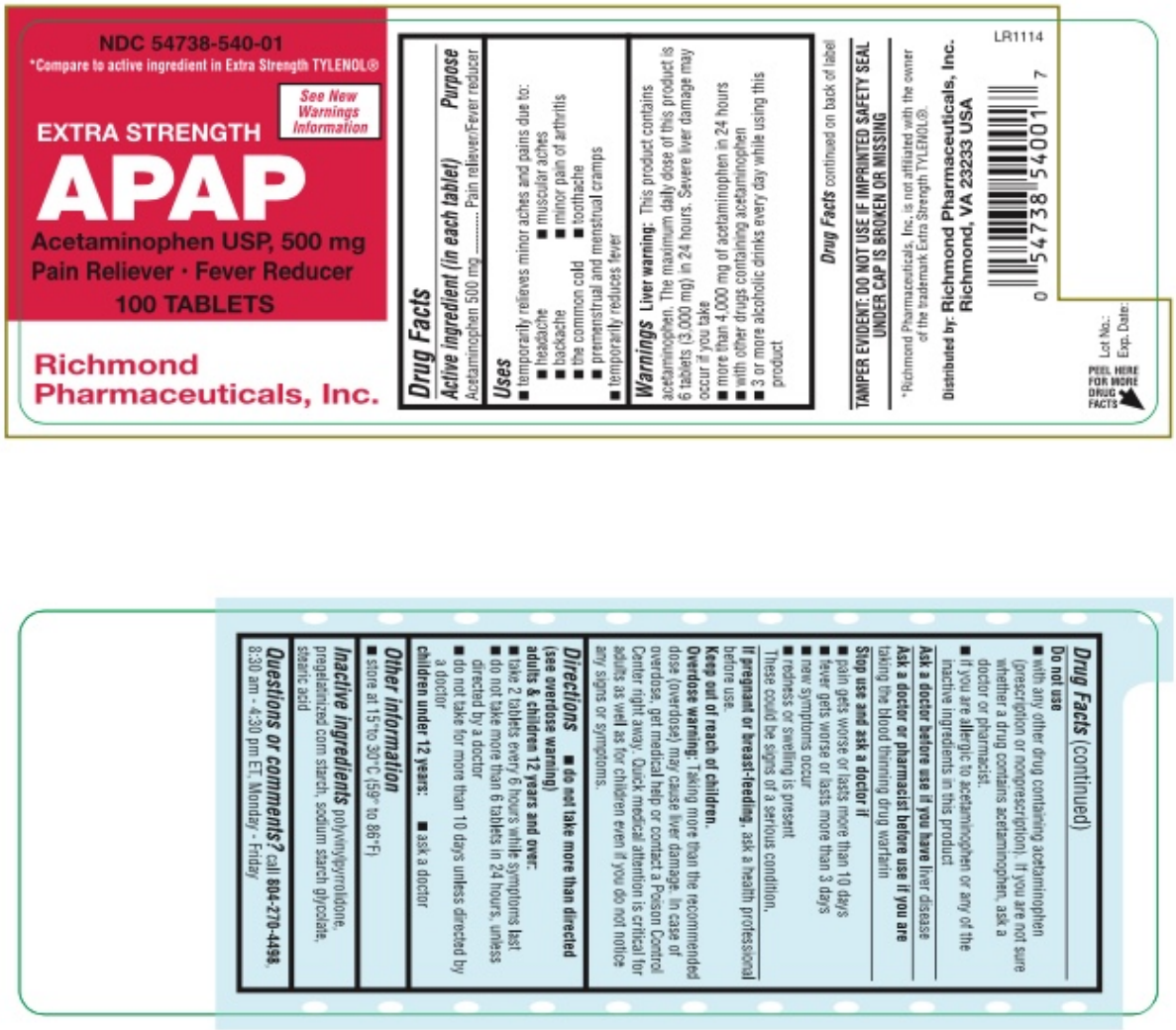
Questions or Comments

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 54738-540-01 ..100 APAP 500mg tabs



NDC: 54738-540-03 ..1000 APAP 500mg tabs

APAP

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54738-540
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)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	AP;013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-540-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	
2	NDC:54738-540-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2015	

Labeler - Richmond Pharmaceuticals, Inc. (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-540)

Revised: 10/2017 Richmond Pharmaceuticals, Inc.