ACETAMINOPHEN- acetaminophen tablet
Brandywine 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.

Acetaminophen USP

Drug Facts

Active ingredient (in each tablet)

Acetaminophen USP, 325 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 or menstrual cramps
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg in 24 hours, which is the maximum daily amount
- child takes more than 5 tablets in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks 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.

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children
- 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.

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 overdose warning)**

adults and children 12 years and over	take 2 tablets every 4-6 hours while symptoms last, not more than 12 tablets in 24 hours
children 6 to 11 years	take 1 tablet every 4-6 hours while symptoms last, not more than 5 tablets in 24 hours
children under 6 years	do not use

Other information

- store at 15° to 30°C (59° to 86°F)

Inactive ingredients

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

Questions or comments?

call **1-800-647-0172,** 8:30 am - 4:30 pm ET, Monday - Friday

Distributed by: **Brandywine Pharmaceuticals, LLC**

PRINCIPAL DISPLAY PANEL - 325 mg Tablet Bottle Label

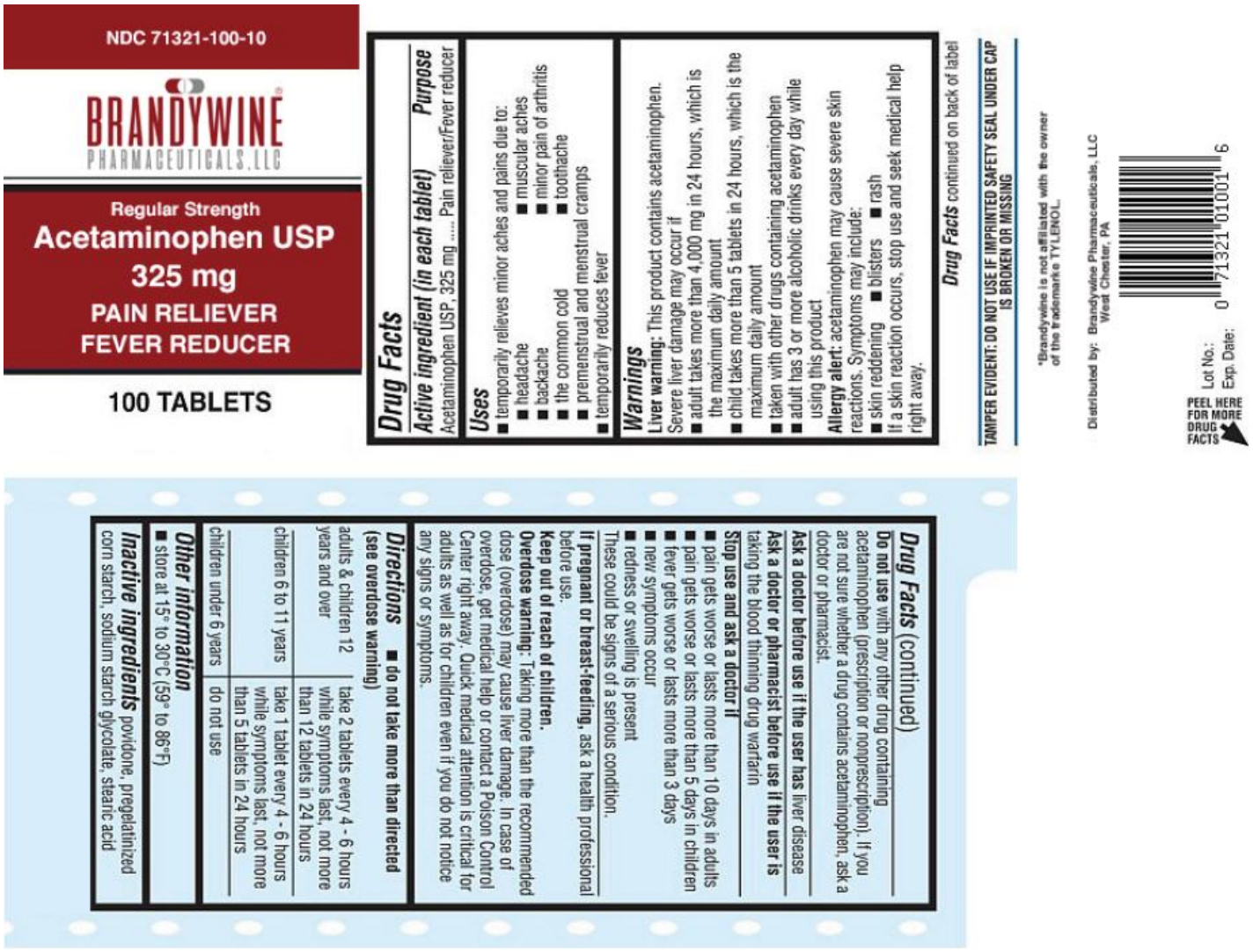
NDC 71321-100-10

BRANDYWINE®
PHARMACEUTICALS,LLC

Regular Strength
Acetaminophen USP
325 mg
PAIN RELIEVER

FEVER REDUCER

100 TABLETS



ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71321-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	BW;99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71321-100-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/26/2017	

Labeler - Brandywine Pharmaceuticals, LLC (080581956)

Establishment

Name	Address	ID/FEI	Business Operations
Brandywine Pharmaceuticals, LLC		080581956	LABEL(71321-100)

Revised: 7/2017 Brandywine Pharmaceuticals, LLC