ACETAMINOPHEN CAPLETS- acetaminophen tablet
Breeden Brothers, 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 Caplets

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

_ temporarily relieves minor aches and pains due to:
_ headache _ the common cold
_ backache _ minor pain of arthritis
_ toothache _ muscular aches
_ premenstrual and menstrual cramps
_ temporarily reduces fever

Drug Facts (continued)

Warnings

Liver warning: This product contains acetaminophen. 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

Allergy alert: Acetaminophen may cause severe skin reactions.

Symptoms may include: _ rash _ blisters

_ skin reddening If a skin reaction occurs, stop use and seek medical help right away.

Do not use

_ if you are allergic to acetaminophen or any of the inactive ingredients in this product

_ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug

Drug Facts (continued)

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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is

Drug Facts (continued)

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

_ 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 12 years: ask a doctor

Other information

_ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

_ use by expiration date on package

Drug Facts (continued)

Inactive ingredients

castor oil, hypromellose, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments?

1-800-901-2420

Dist. by Breeden Brothers, LLC

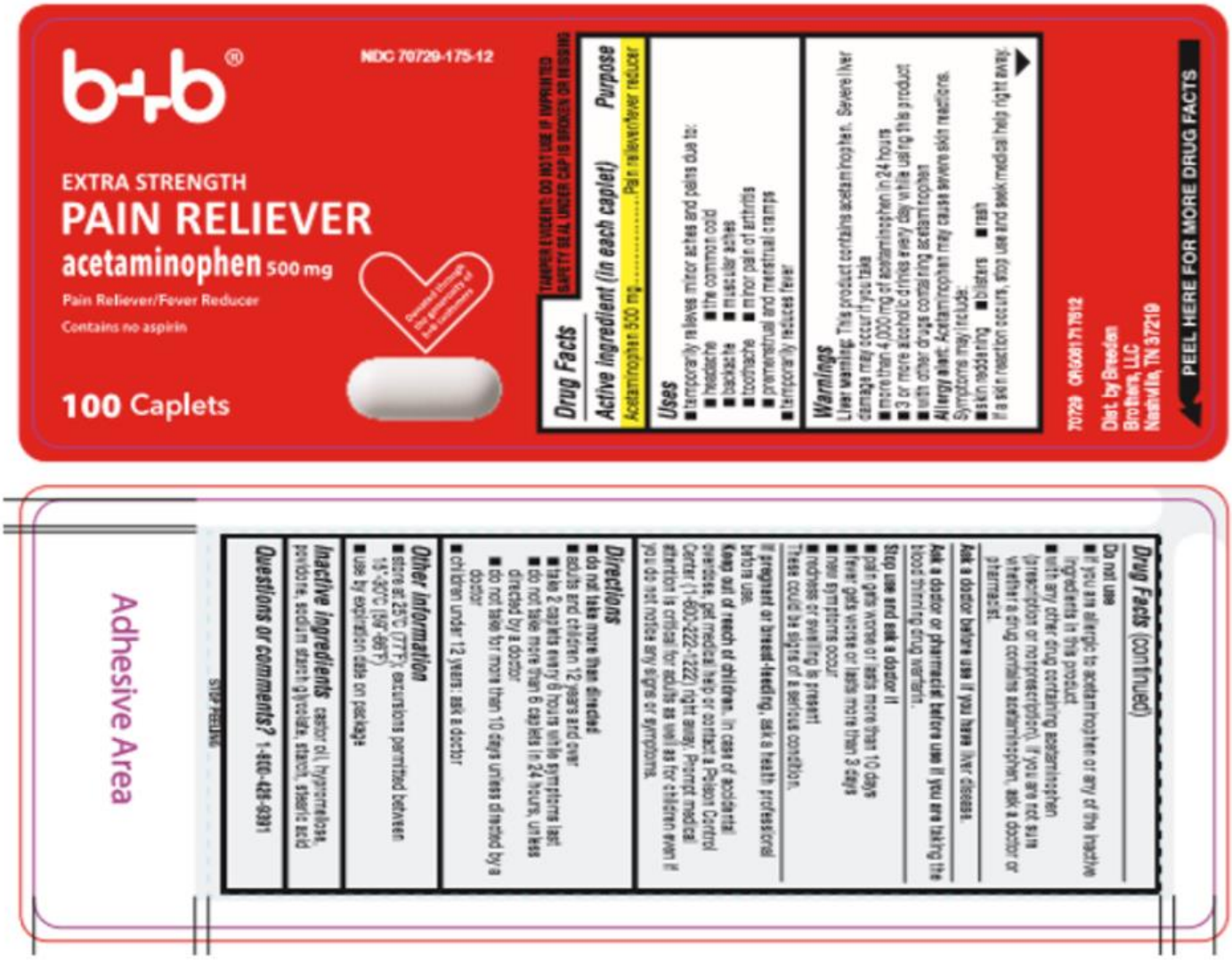
Nashville, TN 37219

PRINCIPAL DISPLAY PANEL

b+b
better by giving
EXTRA STRENGTH
PAIN RELIEVER
acetaminophen
Pain Reliever/Fever Reducer
50 Caplets
(500 mg each)

PRINCIPAL DISPLAY PANEL

b+b
NDC 70729-175-12
EXTRA STRENGTH
PAIN RELIEVER
acetaminophen 500 mg
Pain Reliever/Fever Reducer
100 Caplets



ACETAMINOPHEN CAPLETS

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70729-001
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**
CASTOR OIL (UNII: D5340Y2I9G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
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	OVAL	**Size**	17mm
Flavor		**Imprint Code**	44;175
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70729-001-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2017	
2	NDC:70729-001-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2017	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC MONOGRAPH NOT FINAL	part343	05/01/2017	

ACETAMINOPHEN CAPLETS

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70729-175
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**

CASTOR OIL (UNII: D5340Y2I9G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
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	OVAL	**Size**	17mm
Flavor		**Imprint Code**	44;175
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70729-175-12	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/01/2017	

Labeler - Breeden Brothers, LLC (080131046)

Revised: 2/2017 Breeden Brothers, LLC