EXTRA STRENGTH PAIN RELIEF- acetaminophen tablet
Bryant Ranch Prepack

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.

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gc201

Active Ingredients

Acetaminophen 500 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains
- temporarily reduces fever

Warnings

Liver warning:

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

- more than 8 tablets (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:
• 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 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 symptom 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 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**
- adults and children 12 years and over: Take 1 to 2 tablets every 4 to 6 hours, as needed; not more than 6 tablets in 24 hours. Do not take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

Other Information

- **TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.**
- store at 20ºC-25ºC (68ºF-77ºF)

Inactive Ingredients

povidone, sodium starch glycolate, starch, stearic acid.

Questions or comments?

1-800-540-3765

HOW SUPPLIED

NDC: 63629-1516-1: 20 Tablets in a BOTTLE

NDC: 63629-1516-2: 15 Tablets in a BOTTLE

NDC: 63629-1516-3: 40 Tablets in a BOTTLE

NDC: 63629-1516-4: 100 Tablets in a BOTTLE

NDC: 63629-1516-5: 30 Tablets in a BOTTLE

NDC: 63629-1516-6: 45 Tablets in a BOTTLE

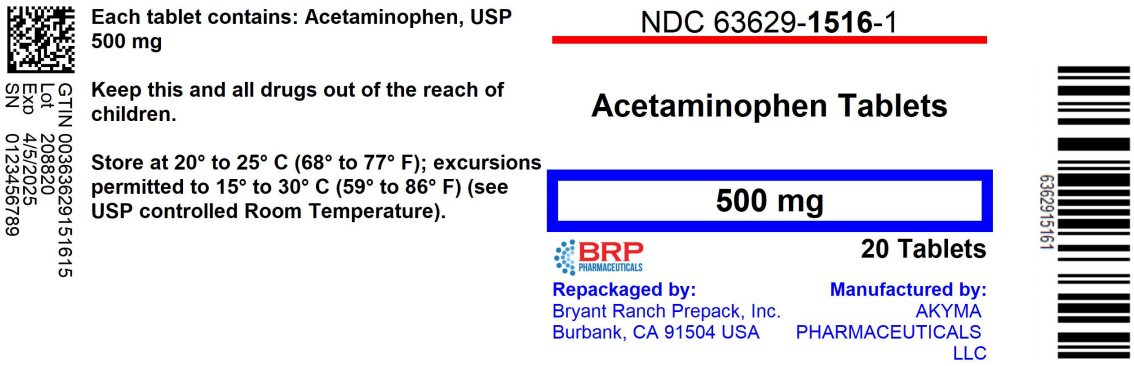
NDC: 63629-1516-7: 50 Tablets in a BOTTLE

NDC: 63629-1516-8: 60 Tablets in a BOTTLE

NDC: 63629-1516-9: 90 Tablets in a BOTTLE

NDC: 63629-1516-0: 250 Tablets in a BOTTLE

Acetaminophen 500mg Tablet



EXTRA STRENGTH PAIN RELIEF

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63629-1516(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**
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white (WHITE)	**Score**	no score
Shape	ROUND (Round)	**Size**	12mm
Flavor		**Imprint Code**	M2A457344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-1516-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2008	
2	NDC:63629-1516-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	
3	NDC:63629-1516-3	40 in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2004	
4	NDC:63629-1516-4	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2006	
5	NDC:63629-1516-5	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2007	
6	NDC:63629-1516-6	45 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2009	
7	NDC:63629-1516-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2008	
8	NDC:63629-1516-8	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2008	
9	NDC:63629-1516-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2010	
10	NDC:63629-1516-0	250 in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/1989	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-1516) , RELABEL(63629-1516)