

## **ACETAMINOPHEN- 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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### **Major Pharmaceuticals Acetaminophen Drug Facts**

#### **Active ingredient (in each caplet)**

Acetaminophen 500 mg

#### **Purpose**

Pain reliever/fever reducer

#### **Uses**

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

#### **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:

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

**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.**

**Overdose warning:** 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	<ul style="list-style-type: none"> <li>• take 2 caplets every 6 hours while symptoms last</li> <li>• do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> <li>• do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

**Other information**

- store at 20-25°C (68-77°F)

## Inactive ingredients

carnauba wax, corn starch\*, croscarmellose sodium\*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid

\*may contain one or more of these ingredients

## Questions or comments?

**1-800-616-2471**

## HOW SUPPLIED

- NDC: 71335-9644-1: 20 Tablets in a BOTTLE
- NDC: 71335-9644-2: 15 Tablets in a BOTTLE
- NDC: 71335-9644-3: 40 Tablets in a BOTTLE
- NDC: 71335-9644-4: 100 Tablets in a BOTTLE
- NDC: 71335-9644-5: 30 Tablets in a BOTTLE
- NDC: 71335-9644-6: 45 Tablets in a BOTTLE
- NDC: 71335-9644-7: 50 Tablets in a BOTTLE
- NDC: 71335-9644-8: 60 Tablets in a BOTTLE
- NDC: 71335-9644-9: 90 Tablets in a BOTTLE
- NDC: 71335-9644-0: 250 Tablets in a BOTTLE

## Acetaminophen 500mg Tablet



GTIN 00371335964412  
Lot 208820  
Exp 6/19/2025  
SN 0123456789

Each tablet contains: Acetaminophen, USP  
500 mg

Keep out of reach of children. In case of  
overdose, get medical help or contact a  
Poison Control Center right away (1-800-222-  
1222).

Store at 20°C - 25°C (68°F - 77°F).

Do not use if printed seal under cap is broken  
or missing.

Do not use with other medicines containing  
acetaminophen.

**NDC 71335-9644-1**

**Acetaminophen Tablets**

**500 mg**

**20 Tablets**



Repackaged by:  
Bryant Ranch Prepack, Inc.  
Burbank, CA 91504 USA

Manufactured by:  
Major  
Pharmaceuticals



## ACETAMINOPHEN

acetaminophen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71335-9644(NDC:0904-6720)
<b>Route of Administration</b>	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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	L484
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-9644-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
2	NDC:71335-9644-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
3	NDC:71335-9644-3	40 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
4	NDC:71335-9644-4	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
5	NDC:71335-9644-5	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
6	NDC:71335-9644-6	45 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
7	NDC:71335-9644-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
8	NDC:71335-9644-8	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
9	NDC:71335-9644-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	
10	NDC:71335-9644-0	250 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/26/2018	

**Labeler** - Bryant Ranch Prepack (171714327)

**Registrant** - Bryant Ranch Prepack (171714327)

## Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-9644) , RELABEL(71335-9644)

Revised: 6/2023

Bryant Ranch Prepack