REGULAR 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.

gc 102

Active Ingredients

Acetaminophen 325 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 tablets in 24 hours. Severe liver damage may occur if you take:

• more than 12 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 2 tablets every 4-6 hours, as needed; not more than 10 tablets in 24 hours
- children under 12 years: ask a doctor

Other Information

• store at 20°C-25°C (68°F-77°F)

Inactive Ingredients

povidone, sodium starch glycolate, starch stearic acid.

HOW SUPPLIED

Product: 71335-1029

NDC: 71335-1029-1 20 TABLET in a BOTTLE NDC: 71335-1029-2 24 TABLET in a BOTTLE NDC: 71335-1029-3 100 TABLET in a BOTTLE

ACETAMINOPHEN 325MG TABLET



REGULAR STRENGTH PAIN RELIEF

acetaminophen tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71335-1029(NDC:57896-102)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	

Inactive Ingredients			
Ingredient Name	Strength		
PO VIDO NE, 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	10 mm	
Flavor		Imprint Code	GC101	
Contains				

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71335-1029-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/19 8 9		
2	NDC:71335-1029-2	24 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/19 8 9		
3	NDC:71335-1029-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/19 8 9		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	0 1/0 1/19 8 9	

Labeler - Bryant Ranch Prepack (171714327)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bryant Ranch Prepack		171714327	REPACK(71335-1029), RELABEL(71335-1029)	

Revised: 2/2019 Bryant Ranch Prepack