CHILDRENS MAPAP- acetaminophen tablet, chewable 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.

Major 44-452

Active ingredient (in each chewable tablet)

Acetaminophen 80 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - sore throat
 - the common cold
 - flu
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

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.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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 your child is allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if your child has

liver disease.

Ask a doctor or pharmacist before use if your child is

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 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.

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 critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (chewable tablets)*
Under 24	Under 2	Ask a doctor
24-35	2-3	2 tablets
36-47	4-5	3 tablets
48-59	6-8	4 tablets
60-71	9-10	5 tablets

72-95 11 6 tablets

*or as directed by a doctor

Other information

- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

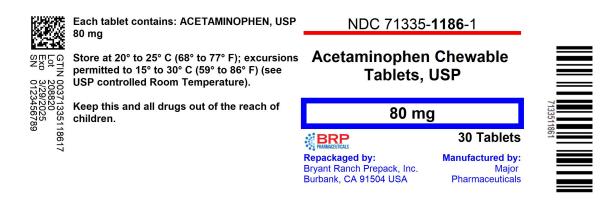
Questions or comments?

(800) 616-2471

HOW SUPPLIED

NDC: 71335-1186-1: 30 Tablets in a BOTTLE

Acetaminophen 80 mg Chewable



CHILDRENS MAPAP acetaminophen tablet, chewable Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71335-1186(NDC:0904-5791) Route of Administration ORAL

Active	Ingredient/Active	Moiety
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STEARIC ACID (UNII: 4ELV7Z65AP) SUCRALOSE (UNII: 96K6UQ3ZD4)

Ingredient Name	Inared	lient	Name	
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Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)

ACETAMINOPHEN

80 mg

Inactive Ingredients				
Ingredient Name	Strength			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
CROSPOVIDONE (UNII: 2S7830E561)				
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)				
D&C RED NO. 30 (UNII: 2S42T2808B)				
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)				
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 30WL53L36A)				
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)				

Product Characteristics				
Color	purple	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	GRAPE	Imprint Code	44;452	
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:71335- 1186-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/19/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	12/06/2004		

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1186), RELABEL(71335-1186)

Revised: 3/2023 Bryant Ranch Prepack