

PAIN AND FEVER- acetaminophen tablet, chewable
A-S Medication Solutions

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.

Rugby Pain & Fever APAP Chewable Tablets

SAVE CARTON FOR COMPLETE DRUG FACTS

Drug Facts

Active ingredient (in each chewable tablet)

Acetaminophen 80 mg

Purposes

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains due to:
- the common cold
- flu
- headache
- sore throat
- toothache
- 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 other drug containing acetaminophen (prescription or non prescription). 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 dose (see overdose warning).

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.

Overdose warning: In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800- 222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

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

Weight	Age	Dosage
Under 24 lbs	Under 2 years	Ask a doctor
24-35 lbs	2-3 years	2 tablets
36-47 lbs	4-5 years	3 tablets
48-59 lbs	6-8 years	4 tablets
60-71 lbs	9-10 years	5 tablets
72-95 lbs	11 years	6 tablets

Other information

- Phenylketonurics: Contains Phenylalanine 14 mg per tablet
- Store at room temperature in a dry place

Inactive ingredients Aspartame, Colloidal Silicon Dioxide, D&C Red #27 Lake, Hypromellose, Magnesium Stearate, Mannitol, Natural and Artificial Berry Flavors, Povidone, Pregelatinized Starch, Sodium Chloride, Sodium Starch Glycolate, Sorbitol, Stearic Acid and Sucralose.

Questions or comments?

Call 1-800-645-2158

Distributed by: **Rugby Laboratories**

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Livonia, MI 48152

www.rugbylaboratories.com

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

HOW SUPPLIED

Product: 50090-3463

NDC: 50090-3463-0 30 TABLET, CHEWABLE in a BOTTLE, PLASTIC / 1 in a CARTON

Acetaminophen



PAIN AND FEVER

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-3463(NDC:0536-1014)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	pink	Score	no score
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Shape	ROUND (ROUND BICONVEX TABLET)		Size	10mm
Flavor	BERRY (Natural and Artificial)		Imprint Code	1G
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3463-0	1 in 1 CARTON	05/24/2018	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	12/01/2013		

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3463)

Revised: 1/2020

A-S Medication Solutions