

ACETAMINOPHEN 80 MG FRUIT CHEW- acetaminophen tablet

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.

ACETAMINOPHEN USP 80 MG FRUIT CHEW TABLET

Drug Facts

Active ingredient (in each tablet)

Acetaminophen USP, 80 mg

Purposes

Pain Reliever/Fever Reducer

Uses

temporarily reduces fever and relieves minor aches and pains caused by

- headache
- the common cold
- flu
- toothache
- sore throat

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if the 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, lasts for more than 2 days or 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 wheater a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if the child has liver disease

Ask a doctor or pharmacist before use if the child is taking the blood thinning drug warfarin

Drug Facts continued on back of label

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

- redness or swelling is present
- any new symptoms appear

These could be signs of a serious condition

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. 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

- **this product does not contain directions or complete warnings for adult use**
- **do not take more than directed (see Overdose warning)**
- find correct dose on chart below
- if possible, use weight to dose, otherwise use age
- chew tablets before swallowing
- give dose every 4 hours while symptoms last
- do not give more than 5 doses in 24 hours

Weight (pounds)	Age (years)	Dose (tablets)
72-95	11-12	4-6
60-71	9-10	4-5
48-59	6-8	4
36-47	4-5	3
24-35	2-3	2
under 24	under 2	ask a doctor

Other information

- **Phenylketonurics: each tablet contains: phenylalanine 5 mg**

Other information

- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

aspartame, compressible sugar, D&C red #27 (Al-lake), dextrose, FD&C yellow #6 (Al-lake), flavors, magnesium stearate, microcrystalline cellulose, stearic acid

Questions or comments?

call 516-341-0666 8:30 am - 4:30 pm ET, Monday - Friday

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

*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark Tylenol®.

Distributed by: **Reliable 1 Laboratories LLC, Valley Stream, NY 11580**

www.reliable1labs.com

HOW SUPPLIED

Product: 50090-3162

NDC: 50090-3162-0 30 TABLET in a BOTTLE, PLASTIC

ACETAMINOPHEN



ACETAMINOPHEN 80 MG FRUIT CHEW

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-3162(NDC:69618-012)
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	pink (Light Pink)	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	AP;051
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3162-0	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/10/2017	



ACETAMINOPHEN 80mg Tablet

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/01/2015	

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3162)

Revised: 6/2018

A-S Medication Solutions