

ACETAMINOPHEN- acetaminophen tablet
Aurohealth LLC

Drug Facts

Active ingredient (in each chewable tablet)

Acetaminophen USP 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - soar 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 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 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 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

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

Weight (lb)	Age (yr)	Dose (tablets)*
under 24	under 2 years	ask a doctor
24 to 35 lbs	2 to 3 years	1 tablet
36 to 47 lbs	4 to 5 years	1½ tablets
48 to 59 lbs	6 to 8 years	2 tablets
60 to 71 lbs	9 to 10 years	2½ tablets

72 to 95 lbs	11 years	3 tablets
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* or as directed by a doctor

Other information

- store between 20° to 25°C (68° to 77°F). Avoid high humidity. Protect from light.
- **do not use if carton is open or if printed seal on blister is broken or missing.**

Inactive ingredients

citric acid anhydrous, colloidal silicon dioxide, copovidone, crospovidone, D&C red No.27 lake, D&C red 30 aluminum lake, dextrose monohydrate, ethylcellulose, flavor, magnesium stearate, mannitol, sodium starch glycolate, stearic acid, sucralose.

Questions or comments?

Call 1-855-274-4122

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 160 mg (48 Chewable Tablets Blister Carton Label)

Healthy Living™

Ages 2-11

DO NOT USE WITH OTHER MEDICINES CONTAINING

ACETAMINOPHEN

CHILDREN'S PAIN RELIEF

acetaminophen chewable tablets 160 mg

Pain Reliever / Fever Reducer

**160 mg
per Tablet**

Pain + Fever

**Chewables - Chew or crush
tablets completely before swallowing**

**Compare
to the active
ingredient in
Children's
Tylenol®
Chewables**

- **Aspirin Free**

• Ibuprofen Free

Bubble Gum Flavor

Actual Size
48 Chewable Tablets
160 mg each



ACETAMINOPHEN
acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-774
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
ETHYLCELLULOSE (4 MPA.S) (UNII: KC5472WRJK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	16mm
Flavor		Imprint Code	F8
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-774-82	8 in 1 CARTON	06/18/2022	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/18/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	manufacture(58602-774)