# CHILDRENS PAIN RELIEF- acetaminophen tablet, chewable Aurohealth LLC

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# **Drug Facts**

# Active ingredient (in each tablet)

Acetaminophen USP 160 mg

# **Purpose**

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 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.

**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 (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 (see overdose warning)
- find right dose on chart below. If possible, use weight to dose; otherwise, use age
- chew before swallowing; this product will soften in mouth for ease of chewing
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (tablets)*
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under 24	under 2 years	ask a doctor
24-35	2-3 years	1 tablet
36-47	4-5 years	1½ tablets
48-59	6-8 years	2 tablets
60-71	9-10 years	2½ tablets
72-95	11 years	3 tablets

<sup>\*</sup> or as directed by a doctor

### Other information

- store at 20° to 25°C (68° to 77°F). Avoid high humidity.
- Tamper Evident: 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

\* This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Children's Tylenol <sup>®</sup> Chewables.

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Distributed by: **AUROHEALTH LLC** 2572 Brunswick Pike Lawrenceville, NJ 08648

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 160 mg (24 Chewable Tablets)

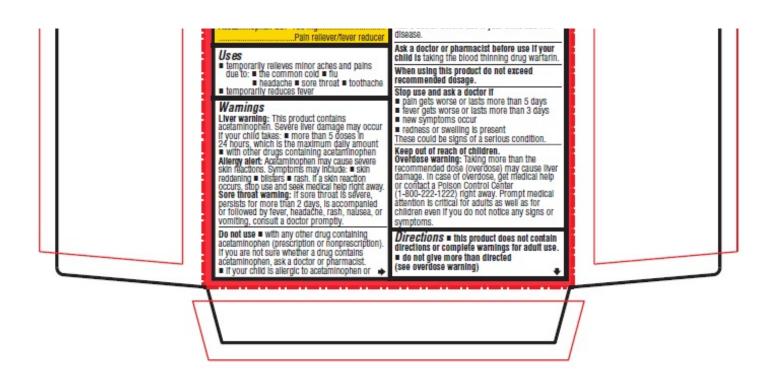
NDC 58602-766-76 Ages 2-11 Children's Pain Relief Acetaminophen 160 mg Pain reliever/Fever reducer

- Aspirin Free
- Ibuprofen Free

# **Bubblegum Flavor**

Compare to the active ingredient in Children's Tylenol® Chewables\* 24 Chewable Tablets





### **CHILDRENS PAIN RELIEF**

acetaminophen tablet, chewable

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58602-766

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 160 mg

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
COPOVIDONE K25-31 (UNII: D9C330MD8B)		
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)		
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)		
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)		
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)		
ETHYLCELLULOSE (4 MPA.S) (UNII: KC5472WRJK)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MANNITOL (UNII: 30WL53L36A)		
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics				
Color	pink	Score	2 pieces	
Shape	ROUND	Size	16mm	
Flavor	BUBBLE GUM	Imprint Code	F8	
Contains				

F	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-766- 76	4 in 1 CARTON	09/13/2017	
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	09/13/2017	

# Labeler - Aurohealth LLC (078728447)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
APL HEALTHCARE LIMITED		650844777	manufacture(58602-766)	

Revised: 11/2023 Aurohealth LLC