

CHILDRENS PAIN RELIEF - acetaminophen tablet, chewable
Aurohealth LLC

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.

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)*
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

* 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® 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

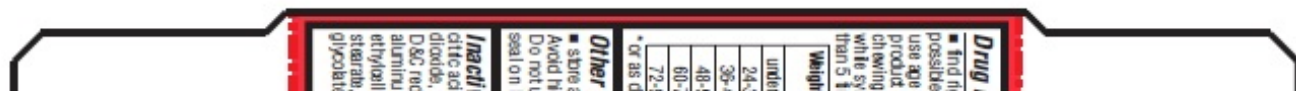
- Aspirin Free
- Ibuprofen Free

Bubblegum Flavor

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

24

Chewable Tablets



Ages 2-11

Children's Pain Relief

Acetaminophen 160 mg

Pain reliever/Fever reducer

Bubblegum Flavor

24
Chewable Tablets

NDC 58602-766-76

Facts (continued)

Take dose on chart below. If use weight to dose; otherwise, chew before swallowing. This will soften in mouth for ease of swallowing. Repeat dose every 4 hours if needed. Do not give more than 5 doses in 24 hours.

Age (yr)	Dose (tablets)
2-4	Under 2 year's ask a doctor
5	2-3 years 1 160 mg
7	4-5 years 1½ tablets
9	6-8 years 2 160 mg
11	9-10 years 2½ tablets
12	11 years 3 160 mg

Directed by a doctor

Information

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). Tamper Evident Seal (TESS) is open or if printed blister is broken or missing.

Active Ingredients

acetaminophen, colloidal silicon dioxide, croscarmellose, croscarmellose sodium, D & W No. 27 (lake), D & W No. 30 (lake), dextrose monohydrate, flavor, magnesium stearate, sodium starch glycolate, succinylated gelatin, sucralose.



Ages 2-11

Children's Pain Relief

Acetaminophen 160 mg

Pain reliever/Fever reducer

Bubblegum Flavor

- Aspirin Free
- Ibuprofen Free

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

24
Chewable Tablets

30620002396
090 # NKU

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING.

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

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



Drug Facts (continued)

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)

Drug Facts

Active ingredient (in each tablet) Purpose
Acetaminophen USP 160 mg.....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

Drug Facts (continued)

Questions or comments? Call 1-855-274-4122

Lot:
EXP:

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: 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	BUBBLE GUM	Imprint Code	F8
Contains			

Packaging

#	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
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Labeler - Aurohealth LLC (078728447)**Establishment**

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	MANUFACTURE(58602-766)

Revised: 12/2020

Aurohealth LLC