

CHILDRENS PAIN RELIEF- acetaminophen tablet, chewable
Aurohealth LLC

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

* 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, FD &C Blue No.1 lake, 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)

AUROHEALTH

NDC 58602-765-76

Ages 2-11

Children's Pain Relief

Acetaminophen 160 mg

Pain reliever/Fever reducer

- **Aspirin Free**
- **Ibuprofen Free**

Grape 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

Grape Flavor

24
Chewable Tablets

NDC 58602-765-76



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

- Aspirin Free
- Ibuprofen Free

Grape Flavor

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

24
Chewable Tablets

5820002006
830 # NKS

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 BUSTER IS BROKEN OR
MISSING.

*This product is not manufactured or
distributed by, under license to,
reseller of, or owned by the registered
trademark owner of the registered
trademark Children's Tylenol®
Chewables.

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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)

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.

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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:58602-765
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	purple	Score	2 pieces
Shape	ROUND	Size	16mm
Flavor	GRAPE	Imprint Code	J26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-765-76	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	Business Operations
APL HEALTHCARE LIMITED		650844777	manufacture(58602-765)

Revised: 11/2023

Aurohealth LLC