# CHILDREN PAIN RELIEF- children pain relief tablet, chewable Allegiant Health

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#### 440 - Children Pain Relief

# Active ingredient(s)

Acetaminophen 160 mg

# **Purpose**

Pain reliever/fever reducer

#### Use(s)

- temporarily relieves minor aches and pains due to:
- headache
- sore throat
- flu
- toothache
- the common cold
- 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

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
- find the 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
- do not give for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (chewable tablets)**
Under 24	Under 2	Ask a doctor
24-35	2-3	1 tablet
36-47	4-5	1 1/2 tablets
48-59	6-8	2 tablets
60-71	9-10	2 1/2 tablets
72-95	11	3 tablets

\*\*or as directed by a doctor

#### Other information

- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

## **Inactive ingredients**

citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol,

polyethylene, stearic acid, sucralose

## **Questions/Comments**

Call 1-888-952-0050 Monday through Friday 9AM - 5PM EST

# **Principal Display Panel**







#### Children's Chewable Tablet

# **CHILDREN PAIN RELIEF**

children pain relief tablet, chewable

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69168-440

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)

ACETAMINOPHEN (UNII: 36209ITL9D) ACETAMINOPHEN 160 mg

# **Inactive Ingredients**

Ingredient Name	Strength

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

CROSPOVIDONE (UNII: 2S7830E561)

D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)

**D&C RED NO. 30** (UNII: 2S42T2808B) **DEXTRATES** (UNII: G263MI44RU)

ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 30WL53L36A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics				
Color	purple	Score	2 pieces	
Shape	ROUND	Size	16mm	
Flavor	GRAPE	Imprint Code	44;449	
Contains				

I	Packaging					
4	# Item Code Package Description		Marketing Start Date	Marketing End Date		
1	NDC:69168-440- 60	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2023			
:	NDC:69168-440- 02	150 in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2024			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/18/2023	

# Labeler - Allegiant Health (079501930)

Revised: 7/2023 Allegiant Health