

CHEWABLE ACETAMINOPHEN CHILDRENS- acetaminophen tablet, chewable
Cardinal Health 110, LLC. DBA Leader

Leader 44-450

Active ingredient (in each chewable tablet)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- 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 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 or crush tablets completely before swallowing; do not swallow tablets whole
- 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

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients

citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

1-800-426-9391

Principal display panel

LEADER™

NDC 70000-0310-1

Children's

Chewable Acetaminophen

160 mg Chewable Tablets | Pain Reliever / Fever Reducer

Bubble Gum Flavor

Ages 2 - 11

Aspirin-Free

Ibuprofen-Free

Chew or crush tablets

completely before swallowing.

24 CHEWABLE TABLETS

ACTUAL SIZE

COMPARE TO

CHILDREN'S TYLENOL®

active ingredient**

100% Money Back Guarantee

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

100%

Money Back

Guarantee

Return to place of purchase.

CIN 5335336 REV. 9/22

**This product is not manufactured or distributed by Johnson & Johnson

Corporation, owner of the registered trademark Children's Tylenol®.
50844 REV0522B45008

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DUBLIN, OHIO 43017
www.myleader.com
1-800-200-6313

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no print / no varnish area
lot no. & exp. date

0 962951 13225 0

CIN 5335336 REV. 9/22

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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Warnings

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Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- hives
- rash
- itching
- swelling
- difficulty breathing

 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.

LEADER

Children's Chewable Acetaminophen
160 mg Chewable Tablets
Pain Reliever / Fever Reducer

NDC 70000-0310-1

Children's Chewable Acetaminophen
160 mg Chewable Tablets | Pain Reliever / Fever Reducer

Bubble Gum Flavor
Ages 2 - 11
Aspirin-Free
Ibuprofen-Free

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24 CHEWABLE TABLETS ACTUAL SIZE

COMPARE TO CHILDREN'S TYLENOL® active ingredient**

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Questions or comments? 1-800-426-9391

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B-0225-450-08
REV0522B45008

Drug Facts (continued)

- 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.

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- pain gets worse or lasts more than 5 days
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Leader 44-450

CHEWABLE ACETAMINOPHEN CHILDRENS			
acetaminophen tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0310
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPROVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	16mm
Flavor	BUBBLE GUM	Imprint Code	44;450
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0310-1	1 in 1 CARTON	02/25/2005	
1		24 in 1 BOTTLE, PLASTIC; 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	02/25/2005	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0310)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0310) , pack(70000-0310)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0310)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0310)

Revised: 10/2024

Cardinal Health 110, LLC. DBA Leader