

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

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**Leader 44-449**

***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.

**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.

**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
- redness or swelling is present
- any new symptoms appear

**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

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (chewable tablets)*</b>
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, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

**Questions or comments?**

**1-800-426-9391**

**Principal display panel**

**LEADER™**

NDC 70000-0309-1

**Children's**

**Chewable Acetaminophen**

**160 mg Chewable Tablets | Pain Reliever / Fever Reducer**

**Grape 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® CHEWABLES**

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 if not satisfied.

**CIN 5335328**

**REV. 02/25**

†This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Children's Tylenol® Chewables. 50844 REV0424C44908

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DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com)

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

100% Money Back Guarantee  
Return to place of purchase if not satisfied.  
CIN 5 335338 REV. 02/25

NDC 70000-0309-1

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

Grape 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<sup>®</sup> CHEWABLES** active ingredient\*

100% Money Back Guarantee

**LEADER<sup>®</sup>**

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

8-025-449-08  
REV04/04/08

**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

<b>Drug Facts</b> <b>Active ingredient (in each chewable tablet)</b> Acetaminophen 160 mg..... Pain reliever/fever reducer	<b>Purpose</b> temporarily relieves minor aches and pains due to: headache sore throat flu toothache the common cold temporarily reduces fever
<b>Uses</b>	<b>Warnings</b> 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 <b>Allergy alert:</b> 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. <b>Sore throat warning:</b> 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.
<b>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.</b> <b>Ask a doctor before use if your child has liver disease.</b>	

**Drug Facts (continued)**

**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, croscollonite, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrans hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

**Questions or comments? 1-800-426-9391**  
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DUBLIN, OHIO 43007  
www.myleader.com  
1-800-200-6313

**Drug Facts (continued)**  
**Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.**

**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  
redness or swelling is present  
any new symptoms appear

**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  
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\*or as directed by a doctor

**Leader 44-449**

**CHEWABLE ACETAMINOPHEN CHILDRENS**

acetaminophen tablet, chewable

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:70000-0309

<b>Route of Administration</b>	ORAL
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### 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 ALUMINUM LAKE (UNII: GE75M6YV5W)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	purple	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	44;449
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0309-1	1 in 1 CARTON	01/28/2005	
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	01/28/2005	

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

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0309)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0309) , pack(70000-0309)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0309)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0309)

Revised: 4/2025

Cardinal Health 110, LLC. DBA Leader