

**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.
- 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

<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®**

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 5335326 REV. 9/22**

\*\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Tylenol®.

50844 REV0522B44908

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
[www.myleader.com](http://www.myleader.com)  
1-800-200-6313

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

0 96295 13224 3

CIN 5355328 REV. 9/22

**100% Money Back Guarantee**  
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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**

**Drug Facts**

**Active ingredient (in each chewable tablet)**  
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  - headache
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- hives
- rash
- if a skin reaction occurs, stop use and seek medical help right away.

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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® active ingredient\*\***

**100% Money Back Guarantee**

LEADER

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

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**Questions or comments? 1-800-426-9391**

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DISTRIBUTED BY: LECORNA HEALTH, LEADER, and LEOX are trademarks of Cardinal Health. All other marks are the property of their respective owners. 1-800-209-6303

8-0225-449-08  
REV0522B44908

**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.**

- stop use and ask a doctor if
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  - 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.

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Leader 44-449

CHEWABLE ACETAMINOPHEN CHILDRENS			
acetaminophen tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0309
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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)	
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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M013	01/28/2005	

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

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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LNK International, Inc.		038154464	pack(70000-0309)
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## 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: 10/2023

Cardinal Health 110, LLC. DBA Leader