

## **PAIN RELIEF CHILDRENS- acetaminophen tablet, chewable**

### **Rite Aid Corporation**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Rite Aid 44-450 Childrens**

#### ***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 accidental 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 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**

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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, dextrans hydrated, ethylcellulose, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

### **Questions or comments?**

1-800-426-9391

*Principal display panel*

**RITE  
AID®  
PHARMACY**

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

**children's  
pain relief  
acetaminophen**

**acetaminophen** 160 mg  
chewable tablets

pain reliever • fever reducer

for children  
ages 2-11

aspirin and  
ibuprofen  
free

bubble gum  
flavored

**chew or crush tablets completely before swallowing.**

ACTUAL SIZE

2 CHEWABLE  
TABLETS

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS  
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

**DISTRIBUTED BY: RITE AID  
30 HUNTER LANE  
CAMP HILL, PA 17011**

**SATISFACTION GUARANTEE**

**IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.**

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

50844 ORG101845024

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



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

# children's pain relief acetaminophen

acetaminophen 160 mg  
chewable tablets  
pain reliever • fever reducer

for children ages 2-11  
aspirin and ibuprofen free

bubble gum flavored



ACTUAL SIZE

2 CHEWABLE TABLETS

chew or crush tablets completely before swallowing.

children's pain relief acetaminophen 160 mg  
chewable tablets  
pain reliever • fever reducer



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DISTRIBUTED BY:  
RITE AID  
30 HUNTER LANE  
CAMP HILL, PA 17011

No print/No varnish  
Lot & Exp date



IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

8-1702-450-24-R  
ORG101845024

**Drug Facts (continued)**

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 ■ 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

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\*or as directed by a doctor

**Other information**

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN  
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Drug Facts (continued)**

■ avoid high humidity  
 ■ see end flap for expiration date and lot number

**Inactive ingredients** citric acid, croscopolidone, 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

50844 ORG101845024  
R-1702-450-24-RDF

**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

**Drug Facts**  
**Active ingredient (in each chewable tablet)**  
 Acetaminophen 160 mg. . . . . Pain reliever/fever reducer

**Purpose**  
 ■ temporarily reduces fever

**Uses**  
 ■ temporarily relieves minor aches and pains due to:  
 ■ headache ■ sore throat ■ ■  
 ■ toothache ■ the common cold  
 ■ temporarily reduces fever

**Warnings**  
 Liver warnings: 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 dose.  
 ■ with other drugs containing acetaminophen  
 Allergic alert: Acetaminophen may cause severe skin reactions. Symptoms may include:  
 ■ rash ■ hives ■ rash  
 ■ skin redness occurs: stop use and seek medical help right away.  
 Store/break 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.  
 ■ if your child has liver disease.  
 Ask a doctor before use if your child has liver disease, the blood thinning drug warfarin, or if your child is taking the blood thinning drug warfarin.  
 When using this product do not exceed recommended dosage.

**Drug Facts (continued)**  
 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.  
 Get out of reach of children. In case of accidental 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.

**Other information**  
 ■ avoid high humidity  
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**Inactive ingredients** citric acid, croscopolidone, 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

PPQ For Box Print-to-Add their QR Barcode here or delete if code is not required before proofing.

Rite Aid 44-450

**PAIN RELIEF CHILDRENS**  
acetaminophen tablet, chewable

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-4450
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)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

## 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:11822-4450-2	1 in 1 CARTON	02/25/2005	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-4450-8	1 in 1 CARTON	02/25/2005	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	02/25/2005	

**Labeler** - Rite Aid Corporation (014578892)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		038154464	PACK(11822-4450)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	MANUFACTURE(11822-4450)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(11822-4450)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	PACK(11822-4450)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	PACK(11822-4450)

Revised: 5/2020

Rite Aid Corporation