# NON-ASPIRIN CHILDRENS- acetaminophen tablet, chewable CHAIN DRUG MARKETING ASSOCIATION INC

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# **Quality Choice 44-449 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

# 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

<sup>\*</sup>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

QC® QUALITY CHOICE

NDC 63868-186-24

\*\*Compare to the Active Ingredient in Children's Tylenol®

Children's

**NON-ASPIRIN** 

Acetaminophen 160 mg Chewable Tablets

#### Pain Reliever / Fever Reducer

Ages 2-11 Pain/Fever

Ibuprofen Free Aspirin Free

Chew or crush tablets completely before swallowing.

Grape Flavor

actual size

**24** CHEWABLE TABLETS

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

Distributed by CDMA, Inc. Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362

# SATISFACTION GUARANTEED 100% QC®

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

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### **Quality Choice 44-449**

# NON-ASPIRIN CHILDRENS

acetaminophen tablet, chewable

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-186
Route of Administration	ORAL		

# **Active Ingredient/Active Moiety**

**SUCRALOSE** (UNII: 96K6UQ3ZD4)

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Ing	rad	ÍΔI	at I	VIЭ	ma
шч	ıeu	пе		чч	ше

**Basis of Strength Strength** 

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)

ACETAMINOPHEN

160 mg

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
<b>D&amp;C RED NO. 30</b> (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: 30WL53L36A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-186- 24	1 in 1 CARTON	01/28/2005	
1		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 Drug	M013	01/28/2005			

# Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>

LNK International, Inc.	038154464	pack(63868-186)	
INK INTERNATIONAL INC	038154464	Dackin 38h8-18h1	

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International Inc		832867837	manufacture(63868-186) pack(63868-186)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(63868-186)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(63868-186)

Revised: 8/2023 CHAIN DRUG MARKETING ASSOCIATION INC