

CHILDRENS PAIN AND FEVER- acetaminophen tablet, chewable
Topco Associates, LLC

TopCare 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

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, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

1-888-423-0139

Principal Display Panel

+TopCare®
health

NDC 36800-449-08

**COMPARE TO CHILDREN'S
TYLENOL® ACTIVE INGREDIENT†**

**children's
Pain & Fever**

ACETAMINOPHEN 160 mg, CHEWABLE TABLETS
PAIN RELIEVER • FEVER REDUCER

• Ibuprofen Free • Aspirin Free

Chew or crush tablets completely before swallowing.

GRAPE
FLAVOR

24 CHEWABLE TABLETS

For Ages
2 to 11 Years

actual size

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

†This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Tylenol®.
50844 REV0522B44908

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QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

Visit here for more information: <http://topbrnds.com/48ZZSG>

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



0 36800 4555 2



NDC 36800-449-08

COMPARE TO CHILDREN'S
TYLENOL® ACTIVE INGREDIENT!

children's Pain & Fever

ACETAMINOPHEN 160 mg, CHEWABLE TABLETS
PAIN RELIEVER • FEVER REDUCER

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GRAPE FLAVOR



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Drug Facts (continued)

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Visit here for more information: <http://topbrnds.com/48ZZSG>

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REV0522844908

Drug Facts (continued)

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TopCare 44-449

CHILDRENS PAIN AND FEVER

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-449
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, 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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-449-08	1 in 1 CARTON	02/15/2019	
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	02/15/2019	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(36800-449)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(36800-449) , pack(36800-449)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-449)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(36800-449)

Revised: 8/2023

Topco Associates, LLC