

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

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.

Topcare 44-450

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, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

1-888-423-0139

Principal display panel

+TopCare®
health

NDC 36800-450-08

**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.

BUBBLE
GUM
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**

QUALITY GUARANTEED

†This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Tylenol®. 50844 REV0522B45008

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QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

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

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



3 69999 450000

QUALITY GUARANTEED

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



NDC 36800-450-08
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.



BUBBLE GUM FLAVOR

24 CHEWABLE TABLETS For Ages 2 to 11 Years actual size



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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
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Do not use

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CHILDRENS PAIN AND FEVER

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-450
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)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:36800-450-08	1 in 1 CARTON	02/15/2019	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part343	02/15/2019	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(36800-450)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(36800-450) , pack(36800-450)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-450)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(36800-450)

Revised: 12/2022

Topco Associates, LLC