

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 44-449

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 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

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

- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- 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.

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 ORG101844908

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007 ©TOPCO LNKA1118
QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com

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

0 36800 445666 2

QUALITY GUARANTEED

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)
Acetaminophen 160 mg Pain reliever/fever reducer

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.



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.



children's Pain & Fever
ACETAMINOPHEN 160 mg, CHEWABLE TABLETS



Scan here for more information

24 CHEWABLE TABLETS

For Ages 2 to 11 Years

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Drug Facts (continued)

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Questions or comments? 1-888-423-0139

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QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com

B-1910-449-08-R
ORG101844908

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
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.

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Top Care 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 (UNII: 2S7830E561)				
D&C RED NO. 27 (UNII: 2LRS185U6K)				
D&C RED NO. 30 (UNII: 2S42T2808B)				
DEXTRATES (UNII: G263MI44RU)				
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)				
Product Characteristics				
Color	PURPLE	Score	no score	
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 NOT FINAL	part343	02/15/2019		

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(36800-449)

Establishment

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

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

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(36800-449)

Revised: 12/2019

Topco Associates, LLC