

CHILDRENS ACETAMINOPHEN- acetaminophen tablet, chewable
WinCo Foods, 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.

Winco 44-449-children

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 (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

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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?

Call **1-800-824-1706** Monday - Friday 9am - 4pm MST

Principal Display Panel

†Compare to the active ingredient in Children's TYLENOL®

WinCo®

FOODS

CHILDREN'S

Acetaminophen

Chewable Tablets

PAIN RELIEVER - FEVER REDUCER

Ibuprofen Free, Aspirin Free

Chew or crush tablets completely before swallowing.

Do not swallow tablets whole.

AGES

2-11

24

Tablets

160 mg EACH

Grape Flavored

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

DISTRIBUTED BY:

WINCO FOODS, LLC, BOISE, ID 83704

†This product is not manufactured or distributed
by JOHNSON & JOHNSON CORPORATION,
distributor of Children's TYLENOL®.

50844 REV1018B44908 WF1905

100% SATISFACTION

GUARANTEE

Comments & Questions? 800-824-1706

OMI T B

Drug Facts (continued)
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Drug Facts (continued)
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
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 ■ 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.
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TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



100% SATISFACTION GUARANTEE
 Comments & Questions? 800-824-1706



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DISTRIBUTED BY:
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 *This product is not manufactured or distributed by JOHNSON & JOHNSON CORPORATION, distributor of Children's TYLENOL®.

B-2150-449-08-R
 REV 1018B44908

WinCo FOODS

CHILDREN'S Acetaminophen

Chewable Tablets

24 TABLETS 160 mg EACH

PAIN RELIEVER - FEVER REDUCER

Compare to the active ingredient in Children's TYLENOL®

WinCo FOODS

CHILDREN'S Acetaminophen

Chewable Tablets

24 Tablets

PAIN RELIEVER - FEVER REDUCER
 Ibuprofen Free, Aspirin Free

AGES 2-11

160 mg EACH
Grape Flavored



Chew or crush tablets completely before swallowing. Do not swallow tablets whole.

CHILDRENS ACETAMINOPHEN

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-311
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
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ETHYLCELLULOSE, UNSPECIFIED (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)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

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:67091-311-24	4 in 1 CARTON	01/28/2005	
1		6 in 1 BLISTER PACK; 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	01/28/2005	

Labeler - WinCo Foods, LLC (056098817)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(67091-311)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(67091-311)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(67091-311)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(67091-311)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(67091-311)