CHILDRENS ACETAMINOPHEN- acetaminophen tablet, chewable WinCo Foods, LLC

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

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

- 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 REV0522C44908 WF2212

100% SATISFACTION GUARANTEE

Comments & Questions? 800-824-1706

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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

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DISTRIBUTED BY:

50844

WF2212 REV0522C44908

Drug Facts (continued)

 ask a doctor or pharmacist.
 if your child is allergic to acetaminophen Do not use
with any other drug containing whether a drug contains acetaminophen nonprescription). If you are not sure acetaminophen (prescription or

in each chewable tablet) ctive ingredient Drug Facts

Purpose

Ask a doctor before use if your child has or any of the inactive ingredients in this

temporarily relieves minor aches and pains

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug

ecommended dosage. When using this product do not exceed

Stop use and ask a doctor if

more than 5 doses in 24 hours, which is

the maximum daily amount

occur if your child takes

liver warning: This product contains acetaminophen. Severe liver damage may

Varnings

temporarily reduces toothache headache

■ sore throat ■ flu ■ the common cold fever

5 days pain gets worse or lasts more than

fever gets worse or lasts more than 3 days

48-59

8

2 tablets

2 1/2 tablets

■ redness or swelling is present These could be signs of a serious condition new symptoms occur

overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as Keep out of reach of children. In case of well as for children even if you do not

notice any signs or symptoms

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

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Questions? Call 1-800-824-1706 Monday – Friday 9am – 4pm MST

Drug Facts (continued)

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache,

ash, nausea, or vomiting, consult a doctor

If a skin reaction occurs, stop use and seek

skin reddening blisters rash evere skin reactions. Symptoms may Illergy alert: Acetaminophen may cause with other drugs containing acetaminophen

nedical help right away.

Directions

use age.

 repeat dose every 4 hours while symptoms swallowing; do not swallow tablets whole

do not give more than 5 times in 24 hours
 do not give for more than 5 days unless

Weight (lb) Inder 24 36-47 Age (yr) Under 2 \$ 2 (chewable tablets) Ask a doctor 1/2 tablets 1 tablet Dose

Drug Facts (continued)

for adult use ITECTIONS this product does not contain directions or complete warnings

do not give more than directed
 find the right dose on chart below. If possible, use weight to dose; otherwise,

chew or crush tablets completely before

WinCo

■ 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

Other information

or as directed by a doctor

see end flap for expiration date and lot

between 15°-30°C (59°-86°F)

CHILDREN'S Acetaminophen

Chewable Tablets

PAIN RELIEVER - FEVER REDUCER

24 TABLETS 160 mg EACH

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

WinCo

CHILDREN'S Acetaminophen

Chewable Tablets

PAIN RELIEVER - FEVER REDUCER Ibuprofen Free, Aspirin Free

160 mg EACH

24 Tablets

Grape Flavored

Chew or crush tablets completely swallowing Do not swallow

B-2150-449-08-R REV0522C44908

Winco 44-449

tablets whole.

Glue Seal NO PRINT AREA

E1024 / LEBG296B

Glue Seal NO PRINT AREA

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
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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)	
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				

Pac	kag	ing

#	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 Drug	M013	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.		832867837	manufacture(67091-311) , 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.		117025878	manufacture(67091-311)

Revised: 1/2024 WinCo Foods, LLC