

PAIN AND FEVER CHILDRENS- acetaminophen tablet, chewable
Walgreen Company

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.

Walgreens 44-450 Childrens-Delisted

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

- **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, dextrans hydrated, ethylcellulose, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

1-800-426-9391

Principal display panel

Walgreens

NDC 0363-4501-08

*Compare to Children's
Tylenol® active ingredient^{††}*

children's

Pain & Fever

ACETAMINOPHEN 160 mg

CHEWABLE TABLETS

PAIN RELIEVER / FEVER REDUCER

CHEWABLE

ASPIRIN FREE

IBUPROFEN FREE

BUBBLEGUM

FLAVOR

ACTUAL SIZE

24 TABLETS

(160 mg each)

SEE NEW DOSING DIRECTIONS

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

AGES

2-11

YEARS

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

Walgreens Pharmacist Recommended

Walgreens Pharmacist Survey

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

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200 WILMOT RD., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED

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50844 REV1018C45008

OR05017-F
REV1118

Drug Facts KEEP OUT OF REACH OF CHILDREN FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each chewable tablet) **Purpose**
Acetaminophen 160 mg 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 redness ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away.
Some 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.

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
■ 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.

Drug Facts (continued)

Directions ■ this product does not contain directions or complete warnings for adult use
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*or as directed by a doctor

Other information
■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTERS 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

Drug Facts (continued)

Inactive ingredients citric acid, croscopolone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrose, hydrated ethylcellulose, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

(Questions or comments? 1-800-426-9391)

No print/No varnish
Lot & Exp date

50844 REV1018C45008

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

Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey
This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Tylenol®.

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Walgreens

children's Pain & Fever
ACETAMINOPHEN 160 mg
CHEWABLE TABLETS
PAIN RELIEVER / FEVER REDUCER

Walgreens

children's Pain & Fever
ACETAMINOPHEN 160 mg
CHEWABLE TABLETS
PAIN RELIEVER / FEVER REDUCER

CHEWABLE BUBBLE GUM FLAVOR

ASPIRIN FREE

IBUPROFEN FREE

24 TABLETS (160 mg each)
SEE NEW DOSING DIRECTIONS
Chew or crush tablets completely before swallowing. Do not swallow tablets whole.

Compare to Children's Tylenol® active ingredient!!

ACTUAL SIZE

AGES 2-11 YEARS



B-2201-450-08-H
REV1018C45008

Walgreens 44-450

PAIN AND FEVER CHILDRENS

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4501
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:0363-4501-08	4 in 1 CARTON	02/25/2005	
1		6 in 1 BLISTER PACK; 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	02/25/2005	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0363-4501)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-4501) , pack(0363-4501)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0363-4501)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0363-4501)

Revised: 1/2023

Walgreen Company