CHILDRENS CHEWABLES- acetaminophen tablet, chewable Strategic Sourcing Services LLC

Foster and Thrive 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

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)
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- see end flap for expiration date and lot number
- avoid high humidity

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?

Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

Principal display panel

NDC 70677-1127-1

Foster & Thrive™

COMPARE TO CHILDREN'S TYLENOL® ACTIVE INGREDIENT**

Children's Chewables Acetaminophen 160 mg Chewable Tablets PAIN RELIEVER/FEVER REDUCER

Ibuprofen Free Ages 2-11 Aspirin Free Bubble Gum Flavored

ACTUAL SIZE

24 CHEWABLE TABLETS

Chew or crush tablets completely before swallowing.

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

**This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Tylenol®. 50844 ORG052245008 Rev. 03/23

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Distributed by:

McKesson Corp., via SSSL., Memphis, TN 38141 Money Back Guarantee www.fosterandthrive.com



NDC 70677-1127-1 **COMPARE TO** CHILDREN'S TYLENOL® Foster & Thrive™ ACTIVE INGREDIENT Children's Chewables Acetaminophen 160 mg Chewable Tablets PAIN RELIEVER/FEVER REDUCER

Ibuprofen Free Ages 2-11 **Aspirin Free Bubble Gum Flavored**

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McKesson Corp, via SSSL, Memphis, TN 38141

ACTUAL SIZE 24 CHEWABLE TABLETS

trademark Children's Tylenol®. 50844 ORG052245008 Johnson & Johnson Corporation, owner of the registered

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■ see end flap for expiration date and lot number ■ avoid high humidity OTHER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR ELISTER IS TORN OR BROKEN

TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR ELISTER IS TORN OR BROKEN noitemioini 19410

Drug Facts (continued)

B-1243-450-08 ORG052245008

EVIDENT: DO NOT USE IF PACKAGE IS OPE IS TORN, BROKEN OR SHOWS ANY SIGNS

NEO OR IF BLISTER UNIT

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

stadets LL 75-96 2 1/2 tablets 9-10 17-03 Stalder S 8-9 69-81 1 1/2 tablets 5-4 74-35 faldst f 2-3 54-39 Ask a doctor Under 2 Under 24 Meight (Ib) Age (yr) Dose (chewable tablets)

■ do not give for more than 5 days unless directed by

or as directed by a doctor

■ do not give more than 5 times in 24 hours ■ repeat dose every 4 hours while symptoms last do not swallow tablets whole chew or crush tablets completely before swallowing;

weignt to dose; otherwise, use age. ■ purp the right dose on chart below. If possible, use ■ do not give more than directed

directions or complete warnings for adult use DIFECTIONS This product does not contain

any signs or symptoms. adults as well as for children even if you do not notice get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for Keep out of reach of children. In case of overdose **Drug Facts** (continued)

These could be signs of a serious condition. m redness or swelling is present

■ uew symptoms occur ■ fever gets worse or lasts more than 3 days ■ pain gets worse or lasts more than 5 days

Stop use and ask a doctor if recommended dosage. When using this product do not exceed

is taking the blood thinning drug wartarin. Ask a dodor or pharmacist before use if your child

Ask a dodor before use if your child has liver

the mactive ingredients in this product if your child is allergic to acetaminophen or any of doctor or pharmadst. ante whether a drug contains acetaminophen, ask a

■ with any other drug containing acetaminophen (preecription or nonpreecription). If you are not esu ton od

doctor promptly. tever, headache, rash, nausea, or vomiting, consult a for more than 2 days, is accompanied or followed by Sore throat warning: If sore throat is severe, persists

Drug Facts (continued)

Children's C<mark>he</mark>wabl

Foster & Thrive"

Chewable Tablets PAIN RELIEVER/FEVER REDUC

Acetaminophen 160

CHEWABLE TABLETS

Foster and Thrive 44-450

CHILDRENS CHEWABLES

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1127
FIGURE TYPE	HOMAN OTC DINGO	itelii code (Source)	NDC./00//-112/

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

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)	
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:70677- 1127-1	4 in 1 CARTON	04/26/2023	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

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	l £ L:
IVIZIVATINA	Intormation
MAINELINA	Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M013	04/26/2023	

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70677-1127)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70677-1127) , pack(70677-1127)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70677-1127)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70677-1127)

Revised: 4/2024 Strategic Sourcing Services LLC