CHILDRENS ACETAMINOPHEN- acetaminophen tablet, chewable United Natural Foods, Inc. dba UNFI

Equaline 44-450-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.

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.

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
- any new symptoms appear
- redness or swelling is present

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

| 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, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

1-855-423-2630

Principal Display Panel

EQUALINE®

compare to Children's Tylenol® Chewables

active ingredient**

NDC 41163-045-08

children's

acetaminophen

160 mg, chewable tablets pain reliever/fever reducer

for ages 2-11

bubble gum flavor

- aspirin free
- ibuprofen free

CHEW OR CRUSH TABLETS COMPLETELY BEFORE SWALLOWING. DO NOT SWALLOW TABLETS WHOLE.

24 chewable tablets

actual size

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 Kenvue Inc., owner of the registered trademark Children's Tylenol® Chewables. 50844 REV0424D45008

100% Quality GUARANTEED

Like it or let us make it right.

That's our quality promise.

855-423-2630

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02903 USA

EQUALINE® children's acetaminophen 160 mg, chewable tablets pain reliever/fever reducer 24 chewable tablets compare to **EQUALINE®** Children's Tylenol® Chewables Drug Facts (continued Questions or comments? 1-855-423-2630 6 TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING NDC 41163-045-08 **This product is not manufactured or distributed by Kenwue Inc. owner of the registered trademark Children's Tylenol® Chewables. 42585 children's acetaminophen No Print/No Varnish 41163 160 mg, chewable tablets Lot & EXP pain reliever/fever reducer for ages 2-11 bubble gum flavor Like it or let us make it right That's our quality promise. 855-423-2630 DISTRIBUTED BY UNFI PROVIDENCE, RI 02903 USA 50844 REV0424D45008 GUARANTEED aspirin free ibuprofen free CHEW OR CRUSH TABLETS COMPLETELY BEFORE SWALLOWING DO NOT SWALLOW TABLETS WHOLE. chewable tablets actual size maximum daily amount with other drugs containing acetaminophen Allergy alert: Acetaminophen may cause If a skin reaction occurs, stop use and seek severe skin reactions. Symptoms may include: more than 5 doses in 24 hours, which is the persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, Sore throat warning: If sore throat is severe medical help right away. occur if your child takes scetaminophen. Severe liver damage may Liver warning: This product contains lin each chewable tablet Active ingredient Drug Facts skin reddening blisters arash varnings temporarily relieves minor aches and pains KEEP OUTER PACKAGE FOR COMPLETE B-0019E-450-08-R REV0424D45008 160 the common sore throat mg fever a cold Purpose do not give more than directed find the right dose on chart below. ■ this product does not contain directions Keep out of reach of children. In case of overdose, get medical help or contact a Poisou Control Center right away. Prompt medical redness or swelling is present ■ pain gets worse or lasts more than 5 days Stop use and ask a doctor if Ask a doctor or pharmacist before use if your child is taking the blood thinning drug Drug Facts (continued) any new symptoms appear Ask a doctor before use if your child has drug contains acetaminophen, ask a doctor or acetaminophen (prescription or nonprescription). If you are not sure whether a Do not use with any other drug containing children even if you do not notice any signs or attention is critical for adults as well as for rarfarin. or complete warnings for adult use fever gets worse or lasts more than 3 days chew or crush tablets completely before possible, use weight to dose; otherwise swallowing; do not swallow tablets whole thinning drug citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) Other information TAMPER EVIDENT: DO NOT USE IF OUTER do not give more than 5 times in 24 hours ■ repeat dose every 4 hours while symptoms dextrates hydrated, ethylcellulose, flavor see end flap for expiration date and lot avoid high humidity Drug Facts (continued) stearic acid, sucralose or as directed by a doctor nactive ingredients Weight (lb) agnesium stearate, mannitol, polyethylene PACKAGE IS OPENED OR BLISTER Under 24 TORN OR BROKEN 72-95 36-47 24-35 48-59 Under 2 Age (yr) 9-10 6.8 2-3 Dose (chewable tablets)*

2 1/2 tablets

1/2 tablets 2 tablets tablet

3 tablets

Ask a doctor

CHILDRENS ACETAMINOPHEN

acetaminophen tablet, chewable

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-045 |
|--------------|----------------|--------------------|---------------|
|--------------|----------------|--------------------|---------------|

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

| mactive myredients | |
|---|----------|
| 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 ALUMINUM LAKE (UNII: GE75M6YV5W) | |
| DEXTROSE MONOHYDRATE (UNII: LX22YL083G) | |
| ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MANNITOL (UNII: 30WL53L36A) | |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | |
| STEARIC ACID (UNII: 4ELV7Z 65AP) | |
| 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:41163-045- 08 | 4 in 1 CARTON | 02/25/2005 | |
| 1 | | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| Maykatina | Information |
|---------------|-------------|
| Marketing | Intormation |
| I'IMI KCCIIIG | |

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|--------------------|----------|------------|------|
| OTC Monograph Drug | M013 | 02/25/2005 | |
| | | | |

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

| Establishment | | | |
|-------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 038154464 | pack(41163-045) |

| Establishment | | | |
|-------------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867837 | manufacture(41163-045) , pack(41163-045) |

| Establishment | | | |
|-------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 967626305 | pack(41163-045) |

| Establishment | | | |
|-------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 117025878 | manufacture(41163-045) |

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