# MEIJER CHILDRENS PAIN AND FEVER REDUCER- acetaminophen tablet, chewable MEIJER DISTRIBUTION INC

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.

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# Children's Pain and Fever Chewables Acetaminophen

#### Active ingredient (in each chewable tablet)

Acetaminophen 160 mg

#### **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - the common cold
  - flu
  - headache
  - sore throat
  - toothache
- 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 reaction. Symptom may include:

- skin reddening
- blister
- rach
- 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 dose (see overdose warning)

# 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.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Quick medical attention is critical 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 (see overdose warning)
- find the right dose on chart below. If possible, use weight to dose; otherwise use age.
- chew completely do not swallow whole
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

| Weight (lbs) | under 24 | 24-35    | 36-47   | 48-59     | 60-71   | 72-95     |
|--------------|----------|----------|---------|-----------|---------|-----------|
| Age (yr)     | under 2  | 2-3      | 4-5     | 6-8 years | 9-10    | 11 years  |
|              | years    | years    | years   |           | years   |           |
| Dose         | ask a    | 1 tablet | 1 ½     | 2 tablets | 2 ½     | 3 tablets |
| (tablets)*   | doctor   |          | tablets |           | tablets |           |

#### Other information

- store at room temperature. Avoid high humidity. Protect from light.
- see end flap for expiration date and lot number

#### **Inactive ingredients**

citric acid, crospovidone, D&C Red No. 30, dextrose, flavor, hydroxypropylcellulose, magnesium stearate, maltodextrin, silicon dioxide, sodium carboxymethylcellulose, starch, sucralose.

#### Questions or comments?

1-866-467-2748

## **Principal Display Panel**

NDC 41250-246-24

Compare to active ingredient in Children's Tylenol® Chewables\*

#### Children's

#### Pain + Fever Chewables

Acetaminophen 160 mg each

Pain reliever/Fever reducer

Aspirin free

Ibuprofen free

**AGES 2-11** 

**Bubblegum Flavor** 

Naturally and Artificially Flavored

24 Chewable Tablets – 160 mg each

# 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 McNeil Consumer Healthcare, owner of the registered trademark Children's Tylenol® Chewables.

**IMPORTANT:** Keep this carton for future reference on full labeling.

### Distributed by:

MEIJER DISTRIBUTION INC

**GRAND RAPIDS, MI, 49544** 

www.meijer.com



# MEIJER CHILDRENS PAIN AND FEVER REDUCER

acetaminophen tablet, chewable

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|----|--------|--------|-------|-------|
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|    | vuu    |        |       | LUUII |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-246

| Active Ingredient/Active Moiety   |                   |          |  |  |  |
|---|-------------------|----------|--|--|--|
| Ingredient Name   | Basis of Strength | Strength |  |  |  |
| ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) | ACETAMINOPHEN     | 160 mg   |  |  |  |

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)                      |          |
| CROSPO VIDO NE (15 MPA.S AT 5%) (UNII: 68401960 MK)                |          |
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)                       |          |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9 XDZ35W2)                     |          |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9 XZ8 H6 N6 OH)        |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                              |          |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D)                                   |          |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)                               |          |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) |          |
| STARCH, CORN (UNII: O8232NY3SJ)                                    |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                                       |          |

| Product Characteristics |            |              |          |  |
|-------------------------|------------|--------------|----------|--|
| Color                   | PINK       | Score        | 2 pieces |  |
| Shape                   | ROUND      | Size         | 16 mm    |  |
| Flavor                  | BUBBLE GUM | Imprint Code | RP160    |  |
| Contains                |            |              |          |  |

| Packaging          |  |                             |                           |  |
|--------------------|--|-----------------------------|---------------------------|--|
| # Item Code        | Package Description                                    | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |
| 1 NDC:41250-246-24 | 4 in 1 CARTON  | 01/29/2020                  |                           |  |
| 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                                  | 01/29/2020           |                    |  |
|                         |  |                      |                    |  |

# Labeler - MEUER DISTRIBUTION INC (006959555)

Revised: 5/2020 MEIJER DISTRIBUTION INC