

JUNIOR STRENGTH PAIN RELIEF - acetaminophen tablet
Capricorn Pharma 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.

Drug Facts

Active Ingredient(in each tablet)

Acetaminophen 160mg

Purpose

Pain Reliever/Fever Reducer

Uses

temporarily relieves minor aches and pains due to:

- the common cold
- flu
- headache
- 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 maximum daily amount
- with other drugs containing acetaminophen

Do not use

- with any other product 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 doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 5 days
- fever gets worse or lasts for more than 3 days

Keep out of reach of children.

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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 exceed recommended dose (see overdose warning)

- find right dose on chart below. If possible, use weight to dose; otherwise, use age
- dissolve in mouth or chew before swallowing
- if needed, repeat dose every 4 hours
- do not use more than 5 times in 24 hours

| | | | | | |
|-------------|--------------|-------|-------|-------|-------------|
| Weight (lb) | Under 48 | 48-59 | 60-71 | 72-95 | 96 and over |
| Age (yr) | Under 6 | 6-8 | 9-10 | 11 | 12 |
| Tablets | Ask a doctor | 2 | 2-1/2 | 3 | 4 |

Other Information

- Do not use if blister unit is broken or shows signs of tampering.
- Store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- See end panel for lot number and expiration date.

Inactive Ingredient

Crospovidone, D & C red # 7, D & C red # 30, ethylcellulose, FD & C blue # 1, flavor, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose, modified starch, polysorbate 80, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, sucralose, talc, triethyl citrate

Principal Display Panel

Capricorn Pharma

ORIGINAL DEVELOPERS AND MANUFACTURERS

Compare to the active ingredient of Junior Tylenol Meltaways

JUNIOR STRENGTH

Pain Relief

ACETAMINOPHEN - 160mg each

For Children Ages 6-11

See new warnings information

- * **Fever Reducer**
- * **Pain Reliever**
- * **Contains no Aspirin**
- * **Melts in your mouth**

RAPIDMELT

24 Fast Dissolving Tablets

Grape Flavor

Drug Facts (continued)

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

Stop use and ask your doctor if ■ new symptoms occur ■ redness or swelling is present

■ pain gets worse or lasts for more than 5 days

■ fever gets worse or lasts for more than 3 days

Keep out of reach of children.

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Drug Facts (continued)

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■ see end panel for lot number and expiration date

Inactive ingredients croscopolone, D&C red #7, D&C red #30, ethylcellulose, FD&C blue #1, flavor, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose, modified starch, polyborate 80, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, sucralose, talc, triethyl citrate

This product is not manufactured or distributed by McNeil-PPC, Inc., owner of the registered trademark "Tylenol" Meltaways. Manufactured by Capricorn Pharma Inc. 6900 English Muffin Way, Unit A Frederick, MD 21703 www.capricornpharma.com

Capricorn Pharma
ORIGINAL DEVELOPERS AND MANUFACTURERS

NDC 66007-145-02

JUNIOR STRENGTH

Pain Relief For Children Ages 6-11

ACETAMINOPHEN - 160 mg each

RAPIDMELT™

Grape Flavor

24 Fast Dissolving Tablets

• **Fever Reducer**
• **Pain Reliever**
• **Contains no Aspirin**
• **Melts in Your Mouth**

SEE NEW WARNINGS INFORMATION

*Compare to the active ingredient of Junior Tylenol® Meltaways

Drug Facts

Active ingredient (in each tablet) Acetaminophen USP 160 mg

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Uses temporarily relieves minor aches and pains due to: ■ the common cold ■ flu

■ headache ■ temporarily reduces fever

Warnings

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■ with other drugs containing acetaminophen

Do not use ■ with any other product 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.**

Capricorn Pharma
ORIGINAL DEVELOPERS AND MANUFACTURERS

JUNIOR STRENGTH

Pain Relief For Children Ages 6-11

ACETAMINOPHEN - 160 mg each

DO NOT SWALLOW WHOLE TABLET

INDIVIDUALLY BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF A BLISTER UNIT IS TORN, BROKEN, OR SHOWS SIGNS OF TAMPERING.

0 000001 000000 0

LOT:
EXP:

JUNIOR STRENGTH PAIN RELIEF

acetaminophen tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66007-145 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 160 mg |

Product Characteristics

| | | | |
|----------|------------------------------|--------------|----------|
| Color | purple (light purple/violet) | Score | 2 pieces |
| Shape | ROUND (Round Lozenge) | Size | 14mm |
| Flavor | GRAPE | Imprint Code | CP |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:66007-145-02 | 4 in 1 CARTON | | |
| 1 | NDC:66007-145-01 | 6 in 1 BLISTER PACK | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 07/26/2010 | |

Labeler - Capricorn Pharma Inc. (041704524)

Registrant - Capricorn Pharma Inc. (041704524)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|---------------------|
| Capricorn Pharma Inc. | | 041704524 | manufacture |