

INFANTS PAIN RELIEVER- acetaminophen suspension
Rij Pharmaceutical Corporation

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 1.6 mL = 2 droppersful)

Acetaminophen 160 mg

Purpose

Fever reducer/ pain reliever

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - immunizations
 - toothache

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

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; taking more than the recommended dose (overdose) may not provide more relief and could cause serious health problems

Stop use and ask a doctor if

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

These could be signs of a serious condition.

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.**
- **shake well before using**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- fill to dose level. Do not use any other dosing device.
- dispense liquid slowly into child's mouth, toward inner cheek.
- if needed, repeat dose every 4 hours while symptoms last.
- do not give use than 5 times in 24 hours
- replace original bottle cap to maintain child resistance
- use only with enclosed dropper
- rinse dropper after each use

Dosing Chart

| Weight (lbs.) | Age (yrs.) | Dose (mL) |
|----------------------|-------------------|------------------------------|
| under 24 | under 2 | ask a doctor |
| 24-35 | 2-3 | 2 droppersful (0.8 + 0.8 mL) |

Attention: Specifically designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing devices.

Other information

- **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING**
- shake well before use.
- Store at room Temperature 15° - 30°C (59° - 86°F)
- protect from freezing.

Inactive ingredients

butyl paraben, cellulose, citric acid, FD&C Blue # 1 FD&C Red # 33, glycerin, high fructose corn syrup, propylene glycol, sodium benzoate, sorbitol, water, xanthan gum

PRINCIPAL DISPLAY PANEL



| INFANTS PAIN RELIEVER | | |
|--|-------------------|--------------------|
| acetaminophen suspension | | |
| Product Information | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) |
| Route of Administration | ORAL | NDC:53807-220 |
| Active Ingredient/Active Moiety | | |
| Ingredient Name | Basis of Strength | Strength |
| Acetaminophen (UNII: 362O9ITL9D) (acetaminophen - UNII:362O9ITL9D) | Acetaminophen | 160 mg in 1.6 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BUTYL PARABEN (UNII: 3QPI1U3FV8) | |
| POWDERED CELLULOSE (UNII: SMD1X3XO9M) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | PURPLE | Score | |
| Shape | | Size | |
| Flavor | GRAPE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53807-220-05 | 1 in 1 CARTON | 03/16/1999 | |
| 1 | | 15 mL in 1 BOTTLE, PLASTIC; 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 | 03/16/1999 | |

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|------------------------|
| Rij Pharmaceutical Corporation | | 144679156 | manufacture(53807-220) |