

INFANTS SILAPAP- acetaminophen solution/ drops
Rebel Distributors Corp

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.

Infant's Silapap Drops

Active Ingredient: Acetaminophen 80 mg (in each 0.8 mL)

Purpose: Fever reducer/pain reliever

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold ■flu ■toothaches ■sore throat ■headaches

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 product 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 dosage. (see overdose warning)**

Stop use and ask a 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.

These could be signs of 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, (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 right dose on chart, if possible use weight to dose; otherwise, use age
- use only enclosed dropper designed for use with this product, do not use any other dosing device
- fill to dose level
- dispense liquid slowly into child's mouth, toward inner cheek
- may be given alone or mixed with formula, milk, juice etc.
- If needed, repeat dose every 4 hours
- do not give more than 5 times in 24 hours
- Replace dropper tightly to maintain child resistance

| Weight (lb) | Age (yr) | Dose (mL) |
|-------------|---------------|-----------------------|
| under 24 | under 2 years | ask a doctor |
| 24-35 | 2-3 years | 1.6 mL (0.8 + 0.8 mL) |

For accurate dosing follow dosing instructions using the enclosed dropper. Fill dropper to 0.8 mL or prescribed level, and dispense with a single firm squeeze of the dropper bulb.

Other information

Store between 20° - 25°C (68° - 77°F)

Inactive ingredients

citric acid, FD&C yellow no. 6, cherry flavor, methylparaben, saccharin sodium, sodium benzoate, sodium citrate, propylene glycol and purified water.

Comments

1-888-974-5279

Manufactured by:

Silarx Pharmaceuticals, Inc.

19 West St.
Spring Valley , NY 10977

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320



INFANTS SILAPAP

acetaminophen solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21695-887(NDC:54838-145) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D) | Acetaminophen | 80 mg in 0.8 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| anhydrous citric acid (UNII: XF417D3PSL) | |
| FD&C yellow no. 6 (UNII: H77VEI93A8) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| saccharin sodium (UNII: SB8ZUX40TY) | |
| sodium benzoate (UNII: OJ245FE5EU) | |
| sodium citrate (UNII: 1Q73Q2JULR) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| water (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHERRY (wild cherry) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:21695-887-15 | 15 mL in 1 BOTTLE, DROPPER | | |
| 2 | NDC:21695-887-30 | 30 mL in 1 BOTTLE, DROPPER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 04/01/1997 | |

Labeler - Rebel Distributors Corp (118802834)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| Rebel Distributors Corp | | 118802834 | RELABEL, REPACK |

Revised: 2/2011

Rebel Distributors Corp