

INFANTS SILAPAP- acetaminophen solution/ drops
Lannett Company, 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.

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.
1033 Stoneleigh Ave.
Carmel , NY 10512



INFANTS SILAPAP

acetaminophen solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

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:54838-145-15	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/01/1997	
2	NDC:54838-145-30	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/01/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	04/01/1997	

Labeler - Lannett Company, Inc. (161630033)

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Lannett Company, Inc.