**CHILDRENS SILAPAP- acetaminophen liquid**
**NuCare Pharmaceuticals,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 Silapap Liquid**

Active Ingredient: Acetaminophen 160 mg (in each 5 mL (TSP))

Purpose: Pain reliever/fever reducer

**Uses** To reduce fever and for the temporary relief of minor aches and pains due to:
- Headache
- Muscular aches
- Backache
- Minor pain of arthritis
- The common cold
- Toothache
- Premenstrual and menstrual cramps

**Warnings**

**Liver Warning:**This product contains acetaminophen. Severe liver damage may occur if you take:
- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**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.

**Alcohol warning:**If the user consumes 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

**Do not use**
- with any other product drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if the user is allergic to acetaminophen or any of the inactive ingredients in this product

**When using this product**
- **do not exceed recommended dose (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 a serious condition

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.**

**Overdose Warning**: In case of overdose, get medical help or contact a Poison Control Center (1800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs of symptoms.

**Directions**
- do not take more than directed (see overdose warning).
- if needed, repeat dose every 4 hours or as directed by a doctor
- do not give more than 5 doses in 24 hours

| | |
|---|---|
| children under 2 yrs (under 24 lbs) | ask a doctor |
| children 2-3 years (24-35 lbs) | 1 teaspoonful (TSP)(5 mL) |
| children 4-5 years (36-47 lbs) | 1 1/2 teaspoonfuls (TSP)(7.5 mL) |
| children 6-8 years (48-59 lbs) | 2 teaspoonfuls (TSP)(10 mL) |
| children 9-10 years (60-71 lbs) | 2 1/2 teaspoonfuls (TSP)(12.5 mL) |
| children 11 years (72-95 lbs) | 3 teaspoonfuls (TSP)(15 mL) |
| adults & children 12 years & older | 4 teaspoonfuls (TSP)(20 mL) |

**Other information**
Store at room temperature 20°-25°C (68°-77°F)

**Inactive ingredients**

citric acid, D&C red no. 33, FD&C red no. 40, cherry flavor, methylparaben, propylene glycol, saccharin sodium, sodium benzoate, and purified water.

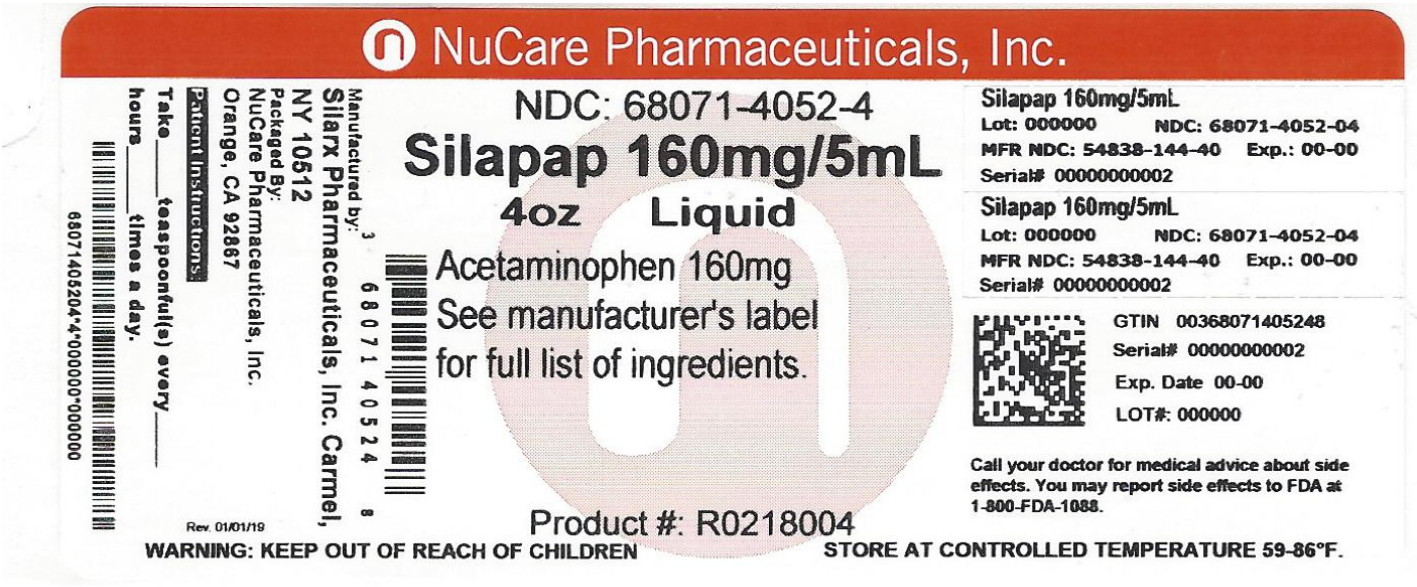
**Questions**

888-974-5279

This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Tylenol ®.

Manufactured by:

Silarx Pharmaceuticals, Inc
1033 Stoneleigh Ave.
Carmel, NY 10512
USA




# CHILDRENS SILAPAP

acetaminophen liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:68071-4052(NDC:54838-144) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 160 mg in 5 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **D&C RED NO. 33** (UNII: 9DBA0SBB0L) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SACCHARIN** (UNII: FST467XS7D) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | CHERRY (cherry flavor) | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:68071-4052-4 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/16/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part343 | 09/05/1994 | |

## Labeler - NuCare Pharmaceuticals,Inc. (010632300)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| NuCare Pharmaceuticals,Inc. | | 010632300 | relabel(68071-4052) |

Revised: 2/2021 NuCare Pharmaceuticals,Inc.