

CHILDRENS SILAPAP - acetaminophen liquid
Silarx 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.

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

SILARXSee New Warnings Information
NDC 54838-144-70**Silapap**
Acetaminophen
LiquidAcetaminophen 160 mg/5 mL
PAIN RELIEVER, FEVER REDUCER

- Alcohol Free
- Aspirin Free
- Sugar Free

DO NOT USE IF PRINTED
SAFETY SEAL ON THE BOTTLE
IS BROKEN OR MISSING**237 mL (8 fl oz)****Drug Facts**

Active ingredient
(in each 5 mL = 1 teaspoon (TSP))
Acetaminophen 160 mg Pain reliever/fever reducer

Purpose

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
 ■ 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 the user should take acetaminophen or other pain relievers/fever reducers.

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 the user is allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has liver disease.
Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

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

Control # & Exp. Date



SEE HERE

N 3 54838-144-70 3

Drug Facts Continued

If pregnant or breastfeeding, 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 (24-36 lbs) 1 teaspoon (TSP) (5 mL)

children 4-5 years (36-47 lbs) 1½ teaspoons (TSP) (7.5 mL)

children 6-8 years (48-89 lbs) 2 teaspoons (TSP) (10 mL)

children 9-10 years (80-71 lbs) 2½ teaspoons (TSP) (12.5 mL)

children 11 years (72-95 lbs) 3 teaspoons (TSP) (15 mL)

adults & children 12 years & older 4 teaspoons (TSP) (20 mL)

Other information

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

Inactive ingredients

citric acid, D&C red no. 88, FD&C red no. 40, cherry flavor, methylparaben, propylene glycol, saccharin sodium, sodium benzoate, and purified water.

Questions ☎ 888-974-8279Manufactured by:
Silarx Pharmaceuticals, Inc.
1033 Stenleight Ave.
Carmel, NY 10512
Rev. 06/13**CHILDRENS SILAPAP**

acetaminophen liquid

Product Information

Product Type HUMAN OTC DRUG

Item Code (Source)

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 sodium dihydrate (UNII: SB8ZUX40TY)	
sodium benzoate (UNII: OJ245FE5EU)	
water (UNII: 059QF0K00R)	

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:54838-144-40	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:54838-144-70	237 mL in 1 BOTTLE, PLASTIC		
3	NDC:54838-144-80	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

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

Labeler - Silarx Pharmaceuticals, Inc (161630033)

Revised: 6/2014

Silarx Pharmaceuticals, Inc