

ACETAMINOPHEN - acetaminophen liquid

H.J. Harkins 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.

Children's Silapap Liquid

Active Ingredient: Acetaminophen 160 mg (in each 5 mL = 1 teaspoonful)

Purpose: Pain reliever/fever reducer

Uses temporarily relieves minor aches and pains due to: the common cold

- flu
- headache
- sore throat
- toothache
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 5 of the recommended doses per day
- 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 you consume 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 containing acetaminophen.

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

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 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 (5 mL)
children 4-5 years (36-47 lbs)	1 1/2 teaspoonfuls (7.5 mL)
children 6-8 years (48-59 lbs)	2 teaspoonfuls (10 mL)
children 9-10 years (60-71 lbs)	2 1/2 teaspoonfuls (12.5 mL)
children 11 years (72-95 lbs)	3 teaspoonfuls (15 mL)
adults & children 12 years & older	4 teaspoonfuls (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
19 West Street
Spring Valley, NY 10977
USA

Repacked by:

H.J. Harkins Company, Inc.
513 Sandydale Drive
Nipomo, CA 93444
USA

52959-309-04

RX Only: #XXXXXXXX

#XXX

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

ACETAMIN. CHILD LIQUID-CHERRY

Lot #: ACL59XS
Mfg: SILARX P.
Exp: 01/10 Compare to: Tylenol
Mfg Spring Valley, Mfg. NDC: 54838-144-40
Loc.: NY Pill ID: Liquid

ACETAMIN. CHILD LIQUID-CHERRY
52959-309-04 Qty 4oz
01/10 Lot ACL59XS
Tylenol 54838-144-40

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Take as directed by your Doctor or
See outsert for usual dosage information

Repack: HJ Harkins Co., Inc. Nipomo., CA 93444
Dispense in light, child & light-resistant container per USP

ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-309(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: A218C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
saccharin sodium (UNII: SB8ZUX40TY)	
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:52959-309-04	118 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 - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
Silarx Pharmaceuticals, Inc		16 1630033	manufacture

Revised: 12/2011

H.J. Harkins Company, Inc.