ACETAMINOPHEN - acetaminophen liquid Physicians Total Care, 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.

Acetaminophen Oral Solution USP 0182-1473-40

Drug Facts

Active ingredient (in each teaspoon (5 mL))	Purpose
Acetaminophen 160 mg	Pain reliever - fever reducer

Uses

for the temporary relief of minor aches and pains associated with

- a cold or flu
- sore throat
- headache
- toothache
- temporarily reduces fever

Warnings

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
- more than directed (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 more than 3 days

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

Keep out of the 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 for adults as well as children even if you do not notice any signs or symptoms.

Directions

- find right dose on chart
- if possible, use weight to dose; otherwise, use age

- if needed, repeat dose every 4 hours
- do not use more than 5 times in 24 hours

Weight	Age	Dose
under 24 lbs	under 2 years	ask a doctor
24 to 35 lbs	2 to 3 years	1 teaspoon (5 mL)
36 to 47 lbs	4 to 5 years	1 ½ teaspoons (7.5 mL)
48 to 59 lbs	6 to 8 years	2 teaspoons (10 mL)
60 to 71 lbs	9 to 10 years	2 ½ teaspoons (12.5 mL)
72 to 95 lbs	11 years	3 teaspoons (15 mL)

Other information

store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

artificial cherry flavor, benzoic acid, citric acid, D&C Red #33, FD&C Red #40, glycerin, polyethylene glycol 1450, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose

Questions?

Call 1-888-838-2872, weekdays, 8 AM - 5 PM Eastern Time

PRINCIPAL DISPLAY PANEL ACETAMINOPHEN

ORAL SOLUTION USP

160 mg/5 mL

PAIN RELIEVER - FEVER REDUCER

Alcohol-Free Aspirin-Free Saccharin-Free Cherry-Flavored

EACH TEASPOON (5 mL) CONTAINS:

Acetaminophen USP 160 mg

TAMPER-EVIDENT: Do not use this product if inner foil seal over the mouth of the bottle is cut, torn, broken or missing.

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Distributed by:

GOLDLINE LABORATORIES, INC.

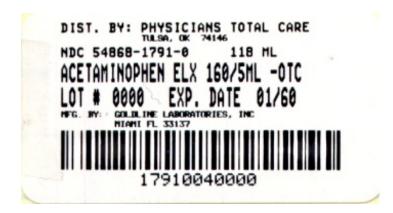
Sellersville, PA 18960 Dist. 1990 0809REV 71

Relabeling of "Additional Barcode Label" by:

Physicians Total Care, Inc.

Tulsa, OK 74146 NDC 54868-1791-0 TAMPER-EVIDENT

ONE PINT (473 mL)



ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54868-1791(NDC:0182-1473)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)
ACETAMINOPHEN (160 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8 M554)	

Product Characteristics				
Color	red	Score		

Shape		Size		
Flavor	CHERRY	Imprint Co	ode	
Contains				
Packaging				
# Item Code	Package Description	Marke	ting Start Date	Marketing End Date
1 NDC:54868-1791-0	473 mL in 1 BOTTLE, PLASTIC			
Marketing Information				
Marketing Category	Application Number or Monograph	h Citation	Marketing Start Dat	e Marketing End Date
				· ·

Labeler - Physicians Total Care, Inc. (194123980)

Establishment				
Name	Address	ID/FEI	Business Operations	
Physicians Total Care, Inc.		194123980	relabel	

Revised: 12/2009 Physicians Total Care, Inc.