

## **ACETAMINOPHEN- acetaminophen liquid**

**Delsam Pharma Llc**

*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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### **Acetaminophen LIQUID**

#### ***Drug Facts***

#### ***Active ingredient (in each 5mL)***

Acetaminophen 160 mg

#### ***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 your child takes:

• more than 5 doses in 24 hours, which is the maximum daily amount • with other drugs containing acetaminophen

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash

If a skin reaction occurs, stop use and seek medical help right away.

**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 dose (see overdose warning)

#### **Stop use and ask a doctor if**

• pain gets worse or last for more than 5 days  
• fever gets worse or last for more than 3 days  
• new symptoms occur • redness or swelling is present  
These could be signs of a serious condition.

**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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

### ***Directions***

- this product does not contain directions or complete warnings for adult use
- find right dose on chart. If possible, use weight to dose; otherwise, use age
- mL = milliliter
- if needed, repeat dose every 4 hours
- do not use more than 5 doses in 24 hours
- use enclosed dosing cup only. Do not use any other device

<b>Weight</b>	<b>Age</b>	<b>Dose</b>
under 24 lbs	Under 2 years	ask a doctor
24 to 35 lbs	2 to 3 years	5mL
36 to 47 lbs	4 to 5 years	7.5mL
48 to 59 lbs	6 to 8 years	10mL
60 to 71 lbs	9 to 10 years	12.5mL
72 to 95 lbs	11 years	15mL

### ***Inactive ingredients***

artificial flavour, Methylparaben, Propylparaben, Potassium sorbate, Citric Acid Monohydrate, Sorbitol, Propylene glycol, Sucralose, Povidone K30, Glycerin, FD&C Red #40, D&C Red #33 & Purified water.

### ***Other information***

- TAMPER EVIDENT: Do not use this product if inner foil seal over mouth of the bottle is cut, torn, broken, or missing.
- store at 20°- 25°C (68° - 77°F)
- this product is not the same concentration as Infants' Drops. For accurate dosing, follow the dosing instructions on this label.

### ***Questions or Comments?***

1-866-826-1306 between 9 am and 4 pm EST, Monday- Friday.

### ***Fast, Effective Relief of Children's Fever and Pain***

- ***Alcohol Free***
- ***Aspirin Free***
- ***Cherry Flavor***

### ***DOSAGE CUP ENCLOSED***

☐ **COMPARE TO the active ingredient of TYLENOL®\*LIQUID**

**TAMPER EVIDENT**

***Child-Resistant Safety Cap Unbreakable Bottle***

\* **Delsam Pharma Llc** is not affiliated with the owner of the registered trademark Tylenol®

Distributed by

**Delsam Pharma Llc**

Bronx, Newyork 10467

**Packaging**

**OUTER BOX LABEL**

**Drug Facts** (continued)

- find right dose on chart. If possible, use weight to dose; otherwise, use age
- mL = milliliter
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**Child-Resistant Safety Cap  
Unbreakable Bottle**

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Mfg. Lic. No.: TN/DRUGS/25/463  
71836-013-04

Distributed by:  
Delsam Pharma Llc  
Bronx, Newyork 10467.



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NDC 72570-100-04  
TAMPER EVIDENT


**Children's**

FEVER REDUCER-PAIN RELIEVER

**Acetaminophen**

**LIQUID**

160mg per 5mL



Delsam Pharma Llc

*Fast, Effective Relief  
of Children's Fever and Pain*

- Alcohol Free
- Aspirin Free
- Cherry Flavor

**DOSAGE CUP  
ENCLOSED**

**COMPARE TO the active  
ingredient of **TYLENOL® LIQUID****

4 Fl. OZ. (118mL)

NDC 72570-100-04  
TAMPER EVIDENT


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4 Fl. OZ. (118mL)

**Drug Facts**

**Active ingredient Purpose**  
(in each 5mL)

Acetaminophen 160 mg... 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 your child takes:  

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NDC 72570-100-04  
TAMPER EVIDENT

**Children's**

FEVER REDUCER-PAIN RELIEVER

**Acetaminophen**

**LIQUID**

160mg per 5mL

Child-Resistant Safety Cap  
Unbreakable Bottle

**INNER LABEL**

NDC 72570-100-04 TAMPER EVIDENT


**Children's**

FEVER REDUCER-PAIN RELIEVER

**Acetaminophen**

**LIQUID**

160mg per 5mL



Delsam Pharma Llc

- Alcohol Free
- Aspirin Free
- Cherry Flavor

4 Fl. OZ. (118mL)

**COMPARE TO the active  
ingredient of **TYLENOL® LIQUID****

**Drug Facts**

**Active ingredient Purpose**  
(in each 5mL)

Acetaminophen 160 mg... Pain reliever - Fever reducer

**Uses**

Temporarily reduces fever For the temporary relief of minor aches and pains associated with the common cold • flu • headache • sore throat • toothache

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes:  

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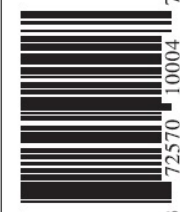
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Mfg. Lic. No.: TN/DRUGS/25/463  
71836-013-04

Distributed by:  
Delsam Pharma Llc  
Bronx, Newyork 10467.

**Lot:**

**Exp:**



3 72570 10004 7

# ACETAMINOPHEN

acetaminophen liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72570-100
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
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POVIDONE K30 (UNII: U725QWY32X)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

Color	red (pinkish red)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72570-100-04	1 in 1 CARTON	09/25/2018	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/25/2018	

**Labeler** - Delsam Pharma Llc (081369679)

Revised: 9/2018

Delsam Pharma Llc