

## **CHILDRENS PAIN RELIEF- acetaminophen liquid Chain Drug Consortium (Premier Value)**

*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 Pain Relief**

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

#### **Active ingredient (in each 5 mL, 1 teaspoon)**

Acetaminophen 160 mg

#### **Purpose**

Pain reliever/fever reducer

#### **Uses**

temporarily:

- reduces fever
- relieves minor aches and pains due to:
  - the common cold
  - flu
  - headache
  - sore throat
  - toothache

#### **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

**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 drug containing acetaminophen (prescription or non-prescription). 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 the child is taking** the blood thinning drug warfarin

##### **When using this product**

- **do not exceed recommended dosage (see overdose warning)**

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

- new symptoms occur

- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts for more than 3 days. These could be signs of a serious condition.

**Keep this and all drugs out of the reach of children.**

### Overdose Warning

Taking more than the recommended dose (overdose) could cause serious health problems including liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center (1-800-222-1222) immediately. Quick medical attention is critical even if you do not notice any signs or symptoms.

### Directions

- **this product does not contain directions or complete warnings for adult use**
- **shake well before using**
- find right dose on chart below. If possible, use weight to dose: otherwise, use age.
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device
- tsp = teaspoon, mL = milliliter
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (tsp or mL)
under 24	under 2	ask a doctor
24-35	2-3	1 tsp or 5 mL
36-47	4-5	1½ tsps or 7.5 mL
48-59	6-8	2 tsps or 10 mL
60-71	9-10	2½ tsps or 12.5 mL
72-95	11	3 tsps or 15 mL

### Other information

- store at controlled room temperature
- dosage cup provided
- each teaspoon contains: sodium 2 mg

### Inactive ingredients

Carboxymethylcellulose, FD&C Blue #1, D&C Red #33, Flavors, Glycerin, High Fructose Corn Syrup, Methylparaben, Microcrystalline Cellulose, Polyethylene Glycol 1450, Propylene Glycol, Propylparaben, Purified Water, Saccharin Sodium, Sorbitol Solution, Sucralose Powder, Xanthan Gum

### Questions or comments?

**1-732-249-6363**

DISTRIBUTED BY  
 CHAIN DRUG CONSORTIUM  
 3301 NW BOCA RATON BLVD  
 SUITE 101, BOCA RATON, FL 33431

**PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label**

NDC 68016-141-04

**Premier Value®**

**Children's Pain Relief  
PAIN RELIEVER - FEVER REDUCER  
ACETAMINOPHEN  
SUSPENSION LIQUID**

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

Grape Flavor

4 FL OZ (118 mL)

**INDEPENDENTLY TESTED  
PV  
SATISFACTION GUARANTEED**

**Drug Facts (continued)**

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 • find right dose on chart below. If possible, use weight to dose; otherwise, use age. • use only enclosed dosing cup designed for use with this product. Do not use any other dosing device  
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**Drug Facts**

**Active ingredient (in each 5 mL, 1 teaspoon)**  
 Acetaminophen 160 mg.....Pain reliever/fever reducer

**Purpose**

**Uses** temporarily. • reduces fever • relieves minor aches and pains due to:  
 • the common cold • flu • headache • sore throat • toothache

**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  
**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 drug containing acetaminophen (prescription or non-prescription). 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 the child is taking the blood thinning drug warfarin**  
**When using this product • do not exceed recommended dosage (see overdose warning)**

**Stop use and ask a doctor if** • new symptoms occur • redness or swelling is present • pain gets worse or lasts more than 5 days • fever gets worse or lasts for more than 3 days. These could be signs of a serious condition.

**Keep this and all drugs out of the reach of children.**  
**Overdose Warning:** Taking more than the recommended dose (overdose) could cause serious health problems including liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center (1-800-222-1222) immediately. Quick medical attention is critical even if you do not notice any signs or symptoms.

**Tamper evident:** Do not use if printed foil seal under cap is torn or missing or printed safety seal on bottle is torn, missing or broken.

**CHILDRENS PAIN RELIEF**

acetaminophen liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-141
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>Acetaminophen</b> (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Carboxymethylcellulose</b> (UNII: 05JZI7B19X)	
<b>Powdered Cellulose</b> (UNII: SMD1X3XO9M)	
<b>Methylparaben</b> (UNII: A2I8C7HI9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>Sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Polyethylene Glycol 1450</b> (UNII: OJ4Z5Z32L4)	
<b>High Fructose Corn Syrup</b> (UNII: XY6UN3QB6S)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>D&amp;C Red No. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C Blue No. 2</b> (UNII: L06K8R7DQK)	
<b>Water</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-141-04	1 in 1 CARTON		
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	10/03/2014	

**Labeler** - Chain Drug Consortium (Premier Value) (101668460)

**Registrant** - davAgen Pharmaceutical, LLC (967545935)

**Establishment**

Name	Address	ID/FEI	Business Operations
davAgen Pharmaceutical, LLC		967545935	MANUFACTURE(68016-141) , PACK(68016-141) , LABEL(68016-141) , ANALYSIS(68016-141)

Revised: 10/2014

Chain Drug Consortium (Premier Value)