

## **INFANTS 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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### **Infant's Pain Relief**

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

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

Acetaminophen 160 mg

#### **Purposes**

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, persist 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 is taking** the blood thinning drug warfarin.

**Ask a Doctor before use if your child has** liver disease.

**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 last 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 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 immediately (1-800-222-1222). 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. If possible, use weight to dose; otherwise use age.
- use only the enclosed syringe designed for use with this product. **Do not use any other dosing device.**
- remove bottle cap and insert syringe into hole at top of bottle and turn upside down.
- pull back plunger of syringe until syringe filled slightly over prescribed level.

Turn to original position, simply push plunger back until you have reached the prescribed level. Pull syringe out of the bottle.

- dispense liquid slowly into baby's mouth, toward the inner cheek.
- if needed repeat dose every 4 hours while symptoms last.
- do not use more than 5 times in 24 hours (see overdose warning).
- replace cap tightly to maintain child resistance.

### Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

**Attention:** use only the enclosed syringe designed for use with this product. Do not use any other dosing device.

### Other information

- store at controlled room temperature
- each 5 mL contains: sodium 2 mg

### Inactive ingredients

Carboxymethylcellulose, Flavor, Glycerin, High Fructose Corn Syrup, Methyl Paraben, Microcrystal Cellulose, Polyethylene Glycol 1450, Propyl Paraben, Propylene Glycol, Purified Water, Saccharin Sodium, Sorbitol, Sucralose, 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 - 59 mL Bottle Label**

NDC 68016-160-02

***Premier  
Value***®

***Infants'  
Pain Relief***

**PAIN RELIEVER - FEVER REDUCER  
ACETAMINOPHEN**

**SUSPENSION LIQUID**

- Dye Free
- Alcohol Free
- Aspirin Free

Use only with  
enclosed syringe

Cherry Flavor

**INDEPENDENTLY TESTED**

***PV***

**SATISFACTION GUARANTEED**

2 FL OZ (59 mL)



NDC 68016-160-02

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### Purposes

Pain reliever/fever reducer

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

### Warnings

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**Sore throat warning:** If sore throat is severe, persist 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 is taking the blood thinning drug warfarin.**

LOT:

EXP:

Peel Here

## Drug Facts (continued)

**Ask a Doctor before use if your child has liver disease.**

**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 last 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 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 immediately (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

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- **shake well before using** • find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only the enclosed syringe designed for use with this product. **Do not use any other dosing device.**
- remove bottle cap and insert syringe into hole at top of bottle and turn upside down.
- pull back plunger of syringe until syringe filled slightly over prescribed level.

## Drug Facts (continued)

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

Turn to original position, simply push plunger back until you have reached the prescribed level. Pull syringe out of the bottle. • dispense liquid slowly into baby's mouth, toward the inner cheek. • if needed repeat dose every 4 hours while symptoms last. • do not use more than 5 times in 24 hours (see overdose warning). • replace cap tightly to maintain child resistance.

Dosing Chart

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24-35	2-3 years	5 mL

**Attention:** use only the enclosed syringe designed for use with this product. Do not use any other dosing device.

**Other information** • store at controlled room temperature • each 5 mL contains: sodium 2 mg

**Inactive ingredients** Carboxymethylcellulose, Flavor, Glycerin, High Fructose Corn Syrup, Methyl Paraben, Microcrystal Cellulose, Polyethylene Glycol 1450, Propyl Paraben, Propylene Glycol, Purified Water, Saccharin Sodium,

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**IMPORTANT: Use enclosed syringe ONLY. DO NOT USE: other dosing device**

Sorbitol, Sucralose, Xanthan Gum

**Questions or comments? 1-732-249-6363**

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

## INFANTS PAIN RELIEF

acetaminophen liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-160
<b>Route of Administration</b>	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
Xanthan Gum (UNII: TTV12P4NEE)	
Carboxymethylcellulose (UNII: 05JZI7B19X)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sucralose (UNII: 96K6UQ3ZD4)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Polyethylene Glycol 1450 (UNII: OJ4Z5Z32L4)	
High Fructose Corn syrup (UNII: XY6UN3QB6S)	
Glycerin (UNII: PDC6A3C0OX)	
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0K00R)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-160-02	1 in 1 CARTON		

1	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
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### 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(68016-160) , PACK(68016-160) , LABEL(68016-160) , ANALYSIS(68016-160)

Revised: 10/2014

Chain Drug Consortium (Premier Value)