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.

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, D & C Red # 33, FD & C Red # 40, 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 68016-178-04

Premier
Value ®

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

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

Bubble
Gum
Flavor

4 FL OZ (118 mL)

INDEPENDENTLY TESTED
PV
SATISFACTION GUARANTEED

CHILDRENS PAIN RELIEF

acetaminophen liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-178
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
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)	
D&C Red No. 33 (UNII: 9DBA0SBB0L)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM, BANANA	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-178-04	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(68016-178) , PACK(68016-178) , LABEL(68016-178) , ANALYSIS(68016-178)