CORE VALUES PAIN AND FEVER- acetaminophen suspension Harmon Stores 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.

Harmon Stores Inc. Pain & Fever Drug Facts

Active ingredient (in each 5 mL)

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

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 drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

• if your child has ever had an allergic reaction to this product or any of its ingredients

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 lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (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
- do not give more than directed (see overdose warning)
- shake well before using
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

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

^{*}or as directed by a doctor

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- each 5 mL contains: sodium 3 mg
- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Principal Display Panel

Compare to active ingredient in Children's Tylenol® Oral Suspension

For Ages 2 to 11 Years

Children's Pain & Fever

Pain Reliever – Fever Reducer

Acetaminophen 160 mg per 5 mL Oral Suspension

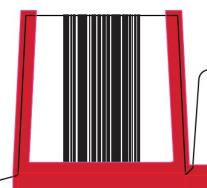
Cherry Flavor

Aspirin Free

Ibuprofen Free

Alcohol Free

4 FL OZ (118 mL)



Fever Children's

COBE NATUES.

CORE VALUES

Compare to active ingredient in Children's Tylenol® Oral Suspension**

For Ages 2 to 11 Years

Children's

Pain Reliever - Fever Reducer Acetaminophen 160 mg per 5 mL Oral Suspension

Cherry Flavor

Aspirin Free Ibuprofen Free Alcohol Free



4 FL OZ (118 mL)





STEP 2. Remove child protective cap

STEP 3.

into the

dosing cup



IMPORTANT:

Please see dosing chart or ask a doctor for your child's correct dose.

Drug Facts

Active ingredient (in each 5 mL)

Purpose

......Pain reliever/fever reducer Acetaminophen 160 mg.

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 maxim

■ more than 5 doses in 24 hours, which is the maximum daily amount of the distribution of the distributio

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.

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor
- or pharmacist.

 if your child has ever had an allergic reaction to this product or any of its ingredients

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 lasts more than 5 days fever gets worse or lasts more than 3 days
- new symptoms occur
 redness or swelling is present
 These could be signs of a serious condition

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical ven if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions

- DIFFECTIONS

 If this product does not contain directions or complete warnings for adult use

 do not give more than directed (see overdose warning)

 shake well before using

 ml = millitier

 find right dose on chart below. If possible, use weight to does or the product of the p

- to dose; otherwise, use age.

 remove the child protective cap and squeeze your child's dose into the dosing cup

 repeat dose every 4 hours while symptoms last
 do not give more than 5 times in 24 hours

ı	Weight (lb)	Age (yr)	Dose (mL)*
ı	under 24	under 2 years	ask a doctor
ı	24-35	2-3 years	5 mL
ı	36-47	4-5 years	7.5 mL
I	48-59	6-8 years	10 mL
ı	60-71	9-10 years	12.5 mL
ı	72-95	11 years	15 mL

72-95 11 ye *or as directed by a doctor

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

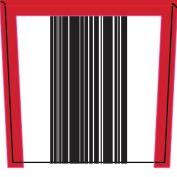
- each 5 mL contains: sodium 3 mg store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or

Inactive ingredients

Inactive ingreatients anhydrous ciric acid, butylepraben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructase com syrup, hydroysthyl cellulose, microcrystalline cellulose and carboxymethycellulose, oddum, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Distributed by Liberty Procurement, Inc. 650 Liberty Ave. Union, NJ 07083 USA Visit us at: www.facevalues.com

SATISFACTION GUARANTEED Or Your Money Back





17526 WR C7

CORE VALUES PAIN AND FEVER

acetaminophen suspension

Product Information

HUMAN OTC DRUG NDC:63940-309 Product Type Item Code (Source)

ORAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CALCIUM SULFATE (UNII: WAT0 DDB505)		
CARRAGEENAN (UNII: 5C69 YCD2YJ)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SODIUM PHO SPHATE, TRIBASIC (UNII: A752Q30A6X)		

Product Characteristics			
Color	RED (opaque)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

]	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-309-26	1 in 1 CARTON	11/06/2017	
1		118 mL in 1 BOTTLE; 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	11/06/2017	

Labeler - Harmon Stores Inc. (804085293)

Revised: 8/2018 Harmon Stores Inc.