

FAST ACTING PEDIA CRAE- acetaminophen suspension
Randob Labs., Ltd.

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.

Crossing well Health Pedia Care Pain + Fever Drug Facts

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 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 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 for adults as well as for children 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. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- 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 cupl specifically designed for use with this product.

Do not use any other dosing device.

Other information

- very low sodium
- store at room temperature

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, sodium benzoate, purified water, sodium citrate dihydrate, sorbitol liquid, sucralose, xanthan gum

Questions?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

NDC 52412-912-01

Fast Acting

Pedia Care®

100% dedicated to kids™

Infants

ACETAMINOPHEN

Pain Reliever / Fever Reducer

Acetaminophen (160mg per 5 mL)

Oral Suspension

- No Added Alcohol
- Ibuprofen Free
- Aspirin Free
- No Parabens

Natural Grape Flavor

(Use only Enclosed Syringe)

1 FL OZ (30 mL)

160 mg per 5 mL

TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL OVER CAP IS BROKEN OR MISSING

IMPORTANT: Keep this carton for future reference on full labeling.

Package Label of 1 FLOZ (30 mL)



Drug Facts

Active ingredient (in each 5 mL) **Purpose**
 Acetaminophen 160 mg 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 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 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 at 1-800-222-1222. Quick medical attention is critical for adults as well as for children 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. If possible, use weight to dose; otherwise, use age. ■ push air out of syringe. Insert syringe tip into bottle opening ■ flip bottle upside down. Pull plunger to correct dose ■ dispense liquid slowly into child's mouth, toward inner cheek ■ repeat dose every 4 hours while symptoms last ■ do not give more than 5 times in 24 hours ■ 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 lbs	2-3 years	5 mL

** or as directed by a doctor

Drug Facts (continued)

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

Other information
 ■ each 5 mL contains: sodium 2 mg
 ■ store at room temperature.

Inactive ingredients anhydrous citric acid, carbocymethylcellulose sodium, flavin, glycerin, microcrystalline cellulose, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol liquid, sucralose, xanthan gum

Questions? 1-833-389-9450

TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL OVER CAP IS BROKEN OR MISSING

IMPORTANT:
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Distributed by
 CrossingWell
 Consumer Health
 PO Box 440
 Cornwall, NY 12518



Infants
ACETAMINOPHEN

NDC 52412-912-01

Fast Acting
PediaCare
 100% dedicated to kids™

Infants
ACETAMINOPHEN

Pain Reliever/
 Fever Reducer
 Acetaminophen (160 mg per 5mL)
 Oral Suspension
 No Added Alcohol, Aspirin Free,
 Ibuprofen Free, No Parabens

Natural Grape Flavor
 (Use Only Enclosed Syringe)
 1 FL OZ (30mL)
 160 mg per 5 mL

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Infants
ACETAMINOPHEN

Pain Reliever/
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 Acetaminophen (160 mg per 5mL)
 Oral Suspension
 No Added Alcohol
 Aspirin Free
 Ibuprofen Free
 No Parabens

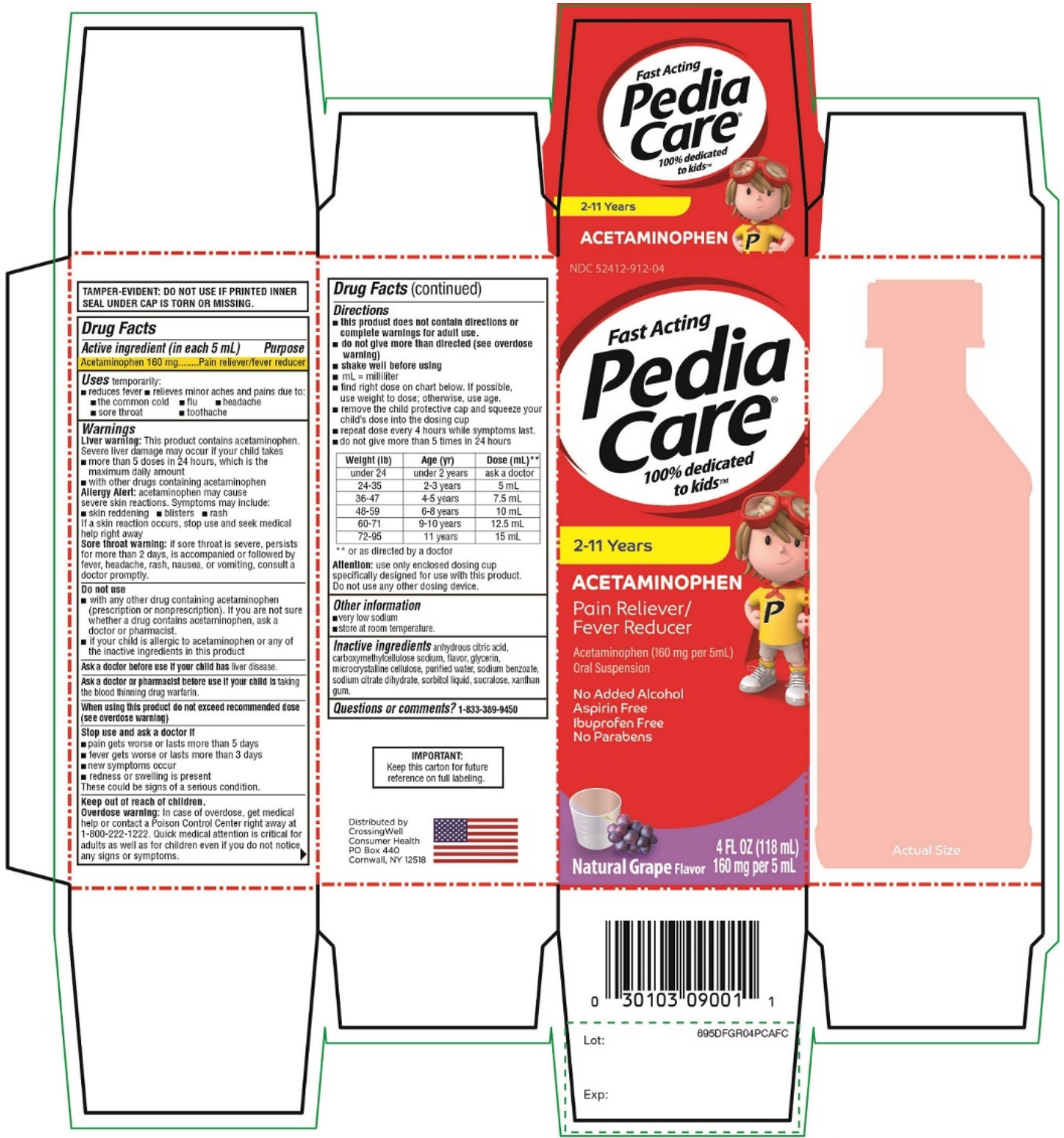
Natural Grape Flavor
 (Use Only Enclosed Syringe)
 1 FL OZ (30mL)
 160 mg per 5 mL

602DFGR01PCAFc

Lot:

Exp:

Package Label of 4 FLOZ (118 mL)



FAST ACTING PEDIA CARE

acetaminophen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:52412-912

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	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)				
GLYCERIN (UNII: PDC6A3C0OX)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-912-01	1 in 1 CARTON	05/26/2023	
1		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:52412-912-04	1 in 1 CARTON	05/26/2023	
2		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	05/26/2023		

Labeler - Randob Labs., Ltd. (061995007)