

**FEVERALL- acetaminophen suspension**  
**TARO PHARMACEUTICALS U.S.A., 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.*

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**FeverAll®**

**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

**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**

Taking more than the recommended dose (overdose) may cause liver damage. 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 below. If possible, use weight to dose; otherwise, use age.
- 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.

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL

36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	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 between 20 to 25°C (68 to 77°F)
- do not refrigerate
- **Keep carton for full directions for use.**

### Inactive ingredients

anhydrous citric acid, butylparaben, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

### Questions?

Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**

Hawthorne, NY 10532

### PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NEW

ORAL

SUSPENSION

LIQUID

NDC 51672-5319-8

CHILDREN'S

ages 2-11 years

FeverAll®

ACETAMINOPHEN (160 mg/5 mL)

Pain Reliever/Fever Reducer

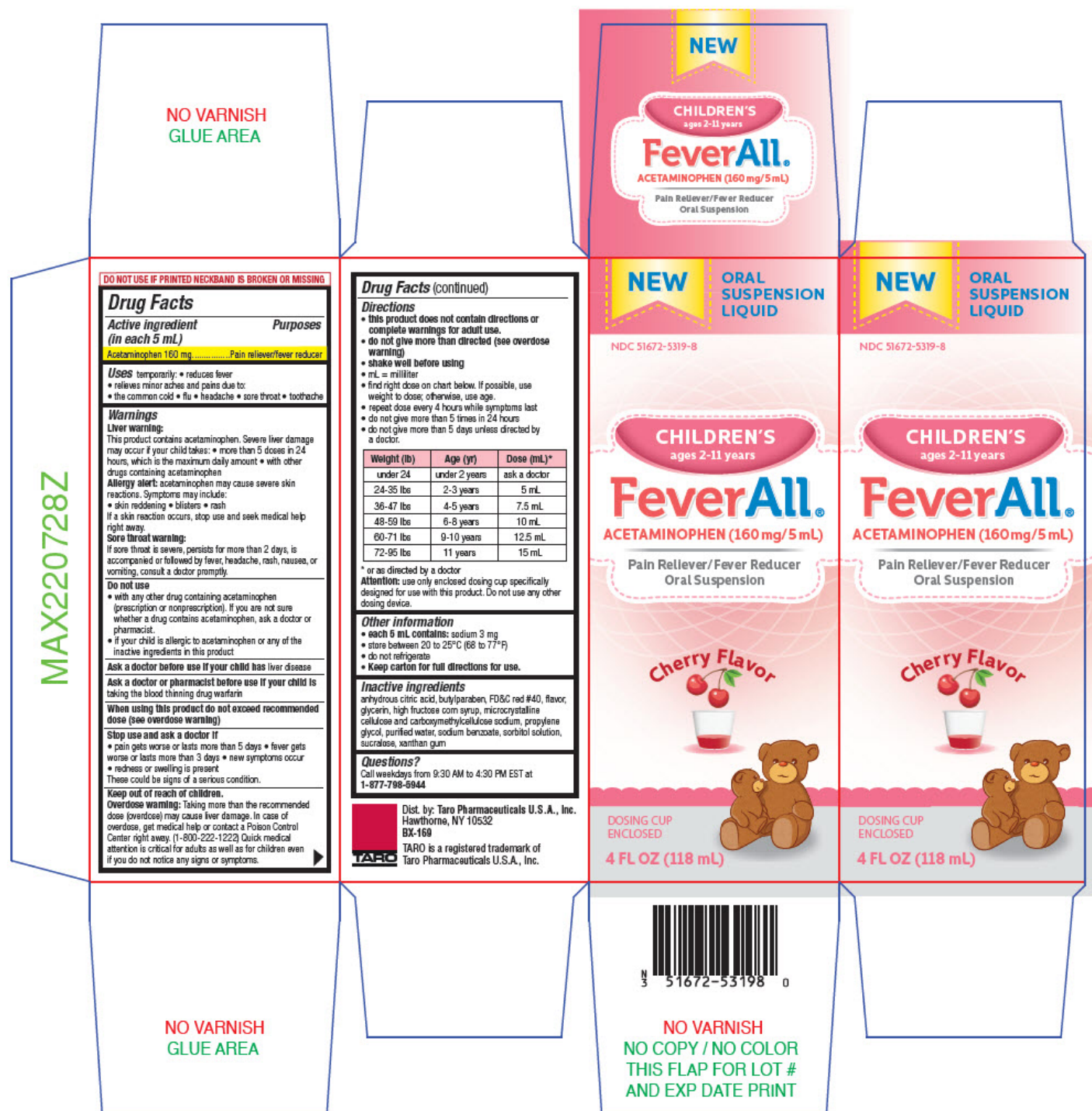
Oral Suspension

Cherry Flavor

DOSING CUP

ENCLOSED

4 FL OZ (118 mL)



## FEVERALL

acetaminophen suspension

### Product Information

#### Product Type

HUMAN OTC DRUG

#### Item Code (Source)

NDC:51672-5319

#### 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)	
butylparaben (UNII: 3QPI1U3FV8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
high fructose corn syrup (UNII: XY6UN3QB6S)	
microcrystalline cellulose (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol solution (UNII: 8KW3E207O2)	
sucralose (UNII: 96K6UQ3ZD4)	
xanthan gum (UNII: TTV12P4NEE)	

## Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-5319-8	1 in 1 CARTON	06/01/2023	
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	06/01/2023	

**Labeler -** TARO PHARMACEUTICALS U.S.A., INC. (145186370)

