

AVEREX- childrens acetaminophen oral suspension suspension
A-Z Pharma Group LLC

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.

A-Z Pharma-AptaPharma Acetaminophen Suspension 118 mL

Active Ingredient(s)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Use

- 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 other of the inactive ingredients in this product.

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 ■ redness or swelling is present. These could be signs of a serious condition.

Keep out of reach of children.

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.

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.
- shake well before using
- mL = milliliter; tsp = teaspoonful
- find the right dose on the chart below. If possible, use weight to dose, otherwise, use age.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor.

Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2 - 3 years	5 mL (1 tsp)
36-47	4 - 5 years	7.5 mL (1 1/2 tsp)
48-59	6 - 8 years	10 mL (2 tsp)
60-71	9 - 10 years	12.5 mL (2 1/2 TSP)
72-95	11 years	15 mL (3 tsp)

*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 (1 tsp) contains; sodium 3 mg
- store between 20-25°C (68-77°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

Package Label - Principal Display Panel

Product Label

Children's Averex

COMPARE TO THE

ACTIVE INGREDIENT IN

CHILDREN'S TYLENOL

ORAL SUSPENSION*

Pain

& Fever

Acetaminophen

Oral Suspension

Pain reliever/Fever Reducer

- Alcohol-Free
- Ibuprofen Free
- Aspirin Free
- For Ages 2 to 11

4 FL OZ (118 mL)

160 mg per 5 mL

Cherry Flavor

DO NOT USE IF PRINTED NECK BAND IS
 BROKEN OR MISSING this
 Product is not manufactured or distributed
 By McNeil Consumer Healthcare, distributor of
 Children's Tylenol Oral Suspension.

Children's Averex

Pain + Fever

Acetaminophen
Oral Suspension

- Alcohol-Free
- Ibuprofen Free
- Aspirin Free
- For Ages 2-11

**Cherry
Flavor**

4 fl oz (118 mL) 160 mg per 5 mL

DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

Active ingredient (in each 5 mL = 1 teaspoonful) 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 **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 a 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

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Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL (1 tsp)
36-47	4-5 years	7.5 mL (1½ tsp)
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60-71	9-10 years	12.5 mL (2½ tsp)
72-95	11 years	15 mL (3 tsp)

*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 (1 tsp) contains: sodium 3 mg ■ store between 20-25°C (68-77°F) ■ do not refrigerate

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 1-877-798-5944

LOT: _____
EXP: _____

Manufactured for: AmeriPharm USA
895 McDonald Ave Brooklyn, NY 11218

DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

Drug Facts

Active ingredient Purpose
 (in each 5 mL = 1 teaspoonful)
 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

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Drug Facts (continued)

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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

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

Manufactured for:
 AmeriPharm USA
 895 McDonald Ave
 Brooklyn, NY 11218

Children's Averex

Acetaminophen (160mg per 5mL) Oral Suspension Ages 2-11

Pain + Fever

Compare to
the active ingredient in
CHILDREN'S TYLENOL®
Oral Suspension

4 fl oz (118 mL)
160 mg per 5 mL

**Cherry
Flavor**

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Acetaminophen (160mg per 5mL) Oral Suspension Ages 2-11

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**Cherry
Flavor**

NDC: 83314-111-11

AVEREX

childrens acetaminophen oral suspension suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83314-111
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
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

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:83314-111-11	1 in 1 CARTON	03/14/2023	
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

03/14/2023

Labeler - A-Z Pharma Group LLC (124947702)

Revised: 3/2023

A-Z Pharma Group LLC