

CHILDRENS ACETAMINOPHEN- acetaminophen suspension
Advagen Pharma Limited

Children's Acetaminophen 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 4 mg
- store at 20-25 °C (68-77 °F)
- **do not use if tamper-evident ring is broken or missing**

Inactive ingredients

edetate disodium, non crystallizing sorbitol solution, carbomer homopolymer, maltitol solution, methylparaben, propylparaben, xanthan gum, sucralose, orange flavor, malic acid, sodium hydroxide, purified water

Questions or comments?

+1-866-488-0312

Distributed by:

Advagen Pharma Ltd.,

East Windsor, NJ 08520, USA

www.advagenpharma.com

Rev. 00, 09/2024

PRINCIPAL DISPLAY PANEL

**Acetaminophen Oral Suspension 16mg/5mL - NDC 72888-459-01 - 118mL
Carton Label**

52 mm X 52 mm
Area
Overprinting

22522

Drug Facts

Active ingredient (in each 5 mL) **Purpose**
Acetaminophen 160 mg.....Pain reliever/fever reducer

Uses temporarily:

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- relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - othache

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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.

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Drug Facts (continued)

Directions

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- 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 pour 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
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72-95	11 years	15 mL

*or as directed by a doctor

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Inactive ingredients

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Questions or comments? +1-866-488-0312

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

Distributed by:
Advagen Pharma Ltd.,
East Windsor, NJ 08520, USA
www.advagenpharma.com
Mfg Lic: MH/104146
Rev.00, 09/2024

NDC 72888-459-01

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

Children's Acetaminophen

160 mg per 5 mL

Oral Suspension

Pain reliever-Fever reducer

**Fast, Effective
Relief Of Children's
Fever And Pain**

- Aspirin free
- ibuprofen free
- Alcohol free

Orange Flavor

For ages 2-11 years

4 fl oz (118 mL)



ADVAGEN

NDC 72888-459-01

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

Children's Acetaminophen

160 mg per 5 mL

Oral Suspension

DIRECTIONS:

STEP 1. Shake well before using



STEP 2. Remove child protective cap



STEP 3. Pour your child's dose into the dosing cup



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

CHILDRENS ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72888-459
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
NONCRYSTALLIZING SORBITOL SOLUTION (UNII: 9E0S3UM200)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
MALTITOL (UNII: D65DG142WK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MALIC ACID (UNII: 817L1N4CKP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72888-459-01	1 in 1 CARTON	02/18/2025	
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 Drug	M013	02/18/2025	

Labeler - Advagen Pharma Limited (051627256)

Revised: 2/2025

Advagen Pharma Limited