

INFANTS PAIN AND FEVER- acetaminophen solution

CVS Pharmacy

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.

Infants' Pain & Fever

Drug Facts

Active Ingredients (in each 5 mL)

Acetaminophen, 160 mg

Purpose

Pain reliever/ fever reducer

Uses

- 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 for this product.
- 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.

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.

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.
- for more than 10 days for pain unless directed by a doctor.
- for more than 3 days for fever unless directed by a doctor.

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.

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.

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

Directions

do not give more than directed (see overdose warning). use the chart below to confirm dose. If possible, use weight to confirm, otherwise use age. ■ give the recommended number of vials below following the instructions under How to Open and Use on the side panel. empty each Single-Use Vial required of all liquid when dosing. 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. this product does not contain directions or complete warnings for adult use.

Dosing Chart

Weight	Age	Dose (mL)
under 24 lbs	under 2 years	Talk to a doctor
24-35 lbs	2-3 years	1 Single-Use Vial (5 mL) Every 4 hours while symptoms last. Do not exceed 5 Single-use Vials in 24 hrs

Other Information

- each Single-Use Vial contains 8mg of sodium.
- store at 20-25 °C (68-77 °F).
- tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken.

Inactive Ingredients

Citric Acid, Cherry Flavor, Edetate Disodium, Glycerin, Maltitol, Polyethylene Glycol, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Metabisulfite, Sorbitol, Sucralose, Trisodium Citrate Dihydrate, Xanthan Gum.

Questions or Comments?

1-800-719-9260

Package Labeling:

CVS Health

Infants' Pain & Fever

Oral Suspension 160 mg/5 mL

Pain reliever/Fever reducer

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

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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.
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.

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.
- for more than 10 days for pain unless directed by a doctor.
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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.

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

Directions

- do not give more than directed (see overdose warning).
- use the chart below to confirm dose. If possible, use weight to confirm, otherwise use age.
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Drug Facts Continued to Side Panel ▶

*This product is not manufactured by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Oral Suspension.

INTEGRATED TAMPER EVIDENT

Push Below to Open

CVS Health

Compare to the active ingredients in Infants' Tylenol® Oral Suspension*

Oral Solution
NDC 69842-258-01

Infants' Pain & Fever

ACETAMINOPHEN

160 mg/5 mL

Pain reliever/Fever reducer

Aspirin, ibuprofen & gluten free

Ages 2-3 years

Alcohol, Sugar & Dye Free

SINGLE-USE VIALS



Cherry Flavor

20 SINGLE-USE VIALS

0.17 fl oz (5 mL) EACH

3.4 fl oz (100 mL) TOTAL

Actual Vial Size on Side Panel

How to Open and Use:



Flick the tip before opening so liquid descends.



Twist the tip until open and discard it immediately.



Place open end into child's mouth and squeeze to dispense all liquid.

WARNING: CHOKING HAZARD Small parts. Keep out of reach of children.

Package Contains 20 Vials

Actual Size



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INFANTS PAIN AND FEVER

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-258
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-258-01	1 in 1 BOX	12/28/2018	
1		100 mL in 1 VIAL; 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	12/28/2018	

Labeler - CVS Pharmacy (062312574)

Revised: 10/2019

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