

PAIN AND FEVER INFANTS- acetaminophen liquid

Walgreens

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily reduces fever
- temporarily relieves minor aches and pains due to:
 - flu
 - the common cold
 - 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 non prescription). 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

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

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 (1-800-222-1222) right away. 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 take more than directed (see Overdose warning)**
- **shake well before using**
- mL = milliliter
- only use the enclosed syringe.

Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.

- remove cap and insert syringe into hole at top of bottle and turn upside down
- pull back syringe until filled to the prescribed level. If you pass the prescribed level, simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
- If needed, 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
- replace cap tightly to maintain child resistance
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (year)	Dose (mL)
under 24	under 2	ask a doctor

24-35	2-3	5 mL
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Other information

- store between 20-25°C (68°-77°F).
- Do not refrigerate.
- see bottom panel for lot number and expiration date

Inactive ingredients

acesulfame potassium, butyl paraben, carboxymethylcellulose sodium, citric acid, FD&C red #40, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to Infants' Tylenol® Oral Suspension active ingredient††
infants'

Pain & Fever

ACETAMINOPHEN 160 mg PER 5 ml

PAIN RELIEVER / FEVER REDUCER

ORAL SUSPENSION

ASPIRIN FREE

IBUPROFEN FREE

ALCOHOL FREE

AGES 2 - 3 YEARS

CHERRY FLAVOR

Use only with enclosed syringe. See side panel for more information.

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE IS BROKEN OR MISSING

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

Package Label

Drug Facts

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

Uses ■ temporarily reduces fever
 ■ temporarily 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 ■ new symptoms occur ■ redness or swelling is present ■ pain gets worse or lasts more than 5 days ■ fever gets worse or lasts more than 3 days
 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 (1-800-222-1222) right away. 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 take more than directed (see Overdose warning)

Drug Facts (continued)

■ shake well before using ■ mL = milliliter
 ■ only use the enclosed syringe. Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child. ■ remove cap and insert syringe into hole at top of bottle and turn upside down
 ■ pull back syringe until filled to the prescribed level. If you pass the prescribed level, simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
 ■ if needed, 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 ■ replace cap tightly to maintain child resistance ■ find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (year)	Dose (mL)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL

*or as directed by a doctor

Other information
 ■ store between 20-25°C (68-77°F)
 ■ do not refrigerate ■ see bottom panel for lot number and expiration date

Inactive ingredients
 aceulfams potassium, butylparaben, carboxymethylcellulose sodium, citric acid, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?
 Call 1-877-753-3936 Monday-Friday 9AM-5PM EST

Walgreens

Compare to Infants' Tylenol®
 Oral Suspension active ingredient††

infants' Pain & Fever

**ACETAMINOPHEN
 160 mg PER 5 mL
 PAIN RELIEVER /
 FEVER REDUCER
 ORAL SUSPENSION**



ASPIRIN FREE

IBUPROFEN FREE

ALCOHOL FREE

AGES 2-3 YEARS

CHERRY FLAVOR



1 FL OZ (30 mL)

Use only with enclosed syringe. See side panel for more information.

Step 1. See Directions for the correct dose for your child.

Step 2. Shake well before using.

Step 3. Push air out of syringe. Firmly push syringe into bottle opening.



Step 4. Turn the bottle upside down. Pull syringe to the first dose line and then push product back into bottle.

Step 5. Pull syringe until it reaches and stays at the correct dose.



Step 6. Dispense liquid slowly into child's mouth.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE IS BROKEN OR MISSING

Walgreens Pharmacist Recommended
 Walgreens Pharmacist Survey
 ††This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Oral Suspension.

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PLD-C268D FC003985

ITEM 351239 W10067-XXXX-L



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ORG0617-F

Lot No:
 Exp. Date:

WALGREENS Infants' Pain & Fever Cherry Flavor

PAIN AND FEVER INFANTS			
acetaminophen liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0132
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
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0132-01	1 in 1 BOX	07/31/2014	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0132-02	1 in 1 BOX	07/31/2014	
2		59 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	07/31/2014	

Labeler - Walgreens (008965063)