TOPCARE PAIN AND FEVER- acetaminophen liquid Topco Associates 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.

Topco Associates LLC. Pain & Fever 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

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 does (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 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. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Firmly push syringe into bottle opening.
- turn bottle upside down. Pull syringe to the first dose line and then push product back into bottle.
- pull syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart			
Weight (lb)	Age (yr)	Dose (mL)*	
under 24	under 2 years	ask a doctor	
24-35	2-3 years	5 mL	

^{*}or as directed by a doctor

• Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

Other information

- store at 20-25°C (68-77°F)
- do not use if printed bottle wrap is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions?

1-888-423-0139

Package/Label Principal Display Panel

SEE NEW DOSAGE & DIRECTIONS

SUSPENSION LIQUID

Infants' Pain & Fever

ACETAMINOPHEN

Fever Reducer

Pain Reliever

Aspirin free

Alcohol free

Ibuprofen free

Use only with enclosed syringe

Pediatrician Preferred Dosing System

See side panel for more information

CHERRY FLAVOR

COMPARE TO INFANTS' TYLENOL® ORAL SUSPENSION active ingredient

1 FL OZ (30 mL)

160 mg per 5 mL

TopCare

SUSPENSION LIQUID

Infants' Pain & Fever

ACETAMINOPHEN CHERRY FLAVOR



NDC 36800-161-10

SEE NEW DOSAGE & DIRECTIONS

SUSPENSION LIQUID

Infants' Pain & Fever

ACETAMINOPHEN

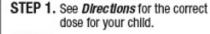
Fever Reducer Pain Reliever

- Aspirin free
- Alcohol free
- Ibuprofen free

Use only with enclosed syringe

Pediatrician Preferred Dosing System

See side panel for more information



- 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.

IMPORTANT:

New Dosage and Directions. Please see dosing chart or ask a doctor for your child's correct dose.

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

CHERRY FLAVOR

COMPARE TO

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INFANTS' TYLENOL® ORAL SUSPENSION active ingredient **

1 Fl 07 (30 ml)

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160 mg per 5 mL

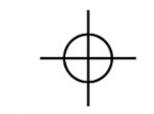


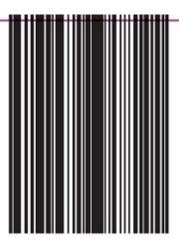


LOT NO.

EXP.

: TPTTO 99 C3







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:
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- flu headache sore throat toothache

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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 redness or swelling is present

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
 new symptoms occur 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 even if you do not notice any signs or symptoms.

Directions this product does not contain directions or complete warnings for adult use

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- turn bottle upside down. Pull syringe to the first dose line and then

Drug Facts (continued)

- pull syringe until it reaches and stavs at the correct dose
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Dosing Chart

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or as directed by a doctor Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

Other information

- store at 20-25°C (68-77°F)
- do not use if printed bottle wrap is broken or missing

Inactive ingredients anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE. IL 60007 1-888-423-0139 @TOPCO PER1213 topcare@topco.com

OUALITY GUARANTEED





TOPCARE PAIN AND FEVER

acetaminophen liquid

Product Information

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:36800-161Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ACETAMINOPHEN (ACETAMINOPHEN)
ACETAMINOPHEN
160 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID		
BUTYLPARABEN		
CALCIUM SULFATE		
CARRAGEENAN		
FD&C RED NO. 40		
GLYCERIN		
HIGH FRUCTO SE CORN SYRUP		
CELLULO SE, MICRO CRYSTALLINE		
CARBO XYMETHYLCELLULO SE SO DIUM		
PROPYLENE GLYCOL		
WATER		
SO DIUM BENZO ATE		
SORBITOL		
SO DIUM PHO SPHATE, TRIBASIC		

Product Characteristics

Color	RED	Score
Shape		Size
Flavor		Imprint Code
Contains		

Pá	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-161-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		
2	NDC:36800-161-16	1 in 1 CARTON		
2		59 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	08/26/2011		

Labeler - Topco Associates LLC (006935977)

Revised: 1/2014 Topco Associates LLC