

EQUALINE INFANTS PAIN AND FEVER- acetaminophen liquid
Supervalu Inc

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.

SuperValu Inc. Infants' 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 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 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 neckband 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 or comments?

1-877-932-7948

Package/Label Principal Display Panel

compare to Infants' Tylenol® Oral Suspension active ingredient

infants'

pain & fever

pain reliever – fever reducer

acetaminophen

suspension liquid

alcohol free

aspirin free

ibuprofen free

pediatrician preferred dosing system

cherry flavor

use only with enclosed syringe

see side panel for more information

2 FL OZ (59 mL)

160 mg per 5 mL

see new dosage & directions

equaline[®]

compare to
Infants' Tylenol[®]
Oral Suspension
active ingredient**

infants'
**pain
& fever**

pain reliever-fever reducer

equaline[®]

compare to
Infants' Tylenol[®]
Oral Suspension
active ingredient**

NDC 41163-161-16

infants'
**pain
& fever**

pain reliever-fever reducer

**acetaminophen
suspension liquid**

- alcohol free
- aspirin free
- ibuprofen free



cherry flavor

pediatrician preferred
dosing system

use only with enclosed syringe
see side panel for more information

2 FL OZ
(59 mL)

see new dosage

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.

IMPORTANT:

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

160 mg per 5 mL

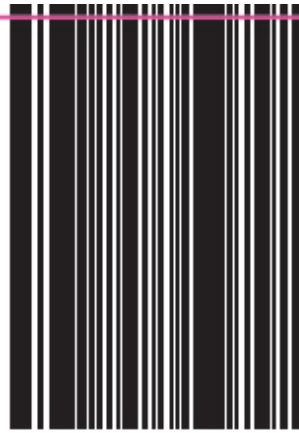
& directions



LOT NO.

EXP.

: 16116 EL C2



Drug Facts

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Acetaminophen 160 mg.....	Pain reliever/fever reducer

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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

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Drug Facts (continued)

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Questions or comments?

1-877-932-7948

GLUTEN FREE

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



We're committed to your satisfaction and guarantee the quality of this product.
 Contact us at 1-877-932-7948, or www.supervalu-ourownbrands.com
 Please have package available.

Distributed by SUPERVALU INC.
 Eden Prairie, MN 55344 USA



EQUALINE INFANTS PAIN AND FEVER

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41163-161
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	
BUTYLPARABEN	
CALCIUM SULFATE	
CARRAGEENAN	
FD&C RED NO. 40	
GLYCERIN	
HIGH FRUCTOSE CORN SYRUP	
CELLULOSE, MICROCRYSTALLINE	
CARBOXYMETHYLCELLULOSE SODIUM	
PROPYLENE GLYCOL	
WATER	
SODIUM BENZOATE	
SORBITOL	
SODIUM PHOSPHATE, TRIBASIC	

Product Characteristics

Color	RED	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-16 1-16	1 in 1 CARTON		
1		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	07/05/2012	

Labeler - Supervalu Inc (006961411)

Revised: 12/2013

Supervalu Inc