

## **EQUALINE CHILDRENS PAIN AND FEVER- acetaminophen suspension**

### **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.*

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### **SuperValu Inc. Children's Pain & Fever Drug Facts**

#### **Active ingredient (in each 5 mL = 1 teaspoonful)**

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; tsp = teaspoonful
- find right dose on chart. 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 or tsp)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL (1 tsp)
36-47	4-5 years	7.5 mL (1 ½ tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2 ½ tsp)
72-95	11 years	15 mL (3 tsp)

\*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 (1 tsp) contains: sodium 3 mg
- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

## Inactive ingredients

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

**Questions or comments?**

1-877-932-7948

**Principal Display Panel**

compare to Children's Tylenol® Oral Suspension active ingredient

for ages 2 to 11

children's pain & fever

pain reliever - fever reducer

acetaminophen oral suspension

alcohol free

aspirin free

ibuprofen free

strawberry flavor

4 FL OZ (118 mL)

160 mg per 5 mL

**equaline**<sup>®</sup>

compare to  
Children's Tylenol<sup>®</sup>  
Oral Suspension  
active ingredient\*\*

children's  
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compare to  
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Oral Suspension  
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NDC 41163-280-26

for ages 2 to 11  
children's

**pain  
& fever**

pain reliever - fever reducer  
**acetaminophen**  
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- alcohol free
- aspirin free
- ibuprofen free



strawberry flavor

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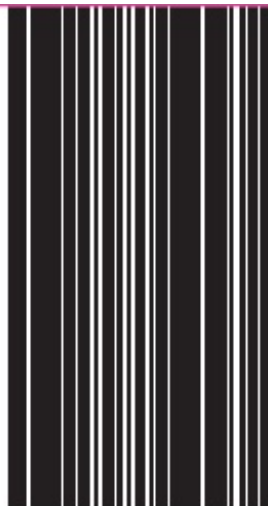


**LOT NO.**

**EXP.**

: 75926 EL C3





### Drug Facts

#### Active ingredient Purpose (in each 5 mL = 1 teaspoonful)

Acetaminophen 160 mg...Pain reliever/fever reducer

#### Uses temporarily:

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

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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

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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#### Questions or comments?

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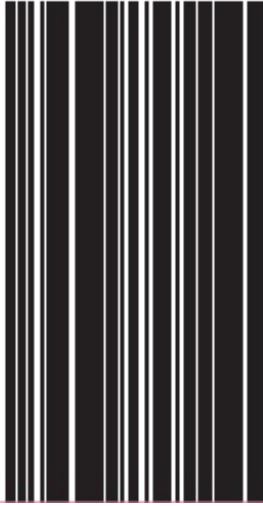
GLUTEN FREE

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

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Eden Prairie, MN 55344 USA

Contact us at 1-877-932-7948, or [www.supervalu-ourownbrands.com](http://www.supervalu-ourownbrands.com)



## EQUALINE CHILDRENS PAIN AND FEVER

acetaminophen suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-280
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-280-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/27/2010	

**Labeler** - Supervalu Inc (006961411)

Revised: 11/2013

Supervalu Inc