

**CHILDRENS PAIN AND FEVER- acetaminophen liquid**  
**AptaPharma 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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**Active ingredient**

**Drug Facts**

**Active ingredient**

(in each 5 mL = 1 teaspoonful)

Acetaminophen 160 mg

**Purpose**

Pain reliever/fever reducer

**Keep out of reach of children**

**Keep out of reach of children.**

**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 is allergic to acetaminophen or any other 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**

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms
- redness or swelling is present These could be signs of a serious condition.

**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 for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

**this product does not contain directions or complete warnings for adult use  
shake well before using**

mL = milliliter; tsp = teaspoonful

find the right dose on the chart below. If possible, use weight to dose, otherwise, use age.

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.

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 1/2 tsp)
48-59	6 - 8 years	10 mL (2 tsp)
60-71	9 - 10 years	12.5 mL (2 1/2 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 between 20-25° C (68-77° F)
- do not refrigerate

**Inactive ingredients**

anhydrous citric acid, butylparaben, FD and C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

**Questions?**

Call weekdays from 9:30 AM to 4:30 PM EST at

**1-877-798-5944**

**Product Label**

**SOUND BODY™**

**COMPARE TO THE ACTIVE INGREDIENTS IN CHILDREN'S TYLENOL® ORAL  
SUSPENSION**

**Children's**

**Pain and Fever**

Acetaminophen

Oral Suspension

Alcohol Free

Ibuprofen Free

Aspirin Free

For Ages 2 to 11

CHERRY FLAVORED

4 FL OZ (118 mL)

160 mg per 5 mL

DO NOT USE IF PRINTED NECKBAND IA BROKEN OR MISSING

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

Manufactured by:

AptaPharma Inc.,

1533 Union Ave

Pennsauken, NJ 08110

V#5002632 ITEM#302

BX-003 Rev 1

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

### Drug Facts

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

#### 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 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

■ 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 for adults as well as for children even if you do not notice any signs or symptoms. ▶

### Drug Facts (continued)

#### Directions

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

■ shake well before using

■ mL = milliliter; tsp = teaspoonful

■ find right dose on chart below. If possible, use weight to dose; otherwise, use age.

■ 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.

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 (1½ tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2½ 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 between 20-25°C (68-77°F)

■ do not refrigerate

#### Inactive ingredients

anhydrous citric acid, butylparaben, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

**Questions?** Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5944

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

Manufactured by:  
AptaPharma Inc.,  
1533 Union Ave.  
Pennsauken, NJ 08110  
V#5002632 ITEM#302

BX-033 Rev 1



COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S TYLENOL® ORAL SUSPENSION\*

Fever Reducer  
Pain Reliever

# Children's Pain & Fever Acetaminophen Oral Suspension

- Alcohol-Free
- Ibuprofen Free
- Aspirin Free

For Ages 2 to 11

CHERRY FLAVOR

4 FL OZ (118 mL)  
160 mg per 5 mL





**DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

**Active Ingredient (in each 5 mL = 1 teaspoonful)** 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  
**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 a 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** ■ pain gets worse or lasts more than 5 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 for adults as well as for children even if you do not notice any signs or symptoms **Directions** ■ this product does not contain directions or complete warnings for adult use. ■ shake well before using ■ mL = milliliter; tsp = teaspoonful ■ find right dose on chart below. If possible, use weight to dose: otherwise, use age. ■ 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.

Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24	under 2 years	ask a doctor
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48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2½ 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 between 20-25°C (68-77°F) ■ do not refrigerate  
**Inactive ingredients** anhydrous citric acid, butylparaben, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum  
**Questions?** Call 1-877-798-5944  
 LOT:  
 Manufactured by: AptarPharma Inc.,  
 1533 Union Ave, Pennsauken, NJ 08110  
 V#5002632 ITEM#302 LR-056 Rev 1 EXP:

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## CHILDRENS PAIN AND FEVER

acetaminophen liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-302
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)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
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)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-302-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/21/2013	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/21/2013	

**Labeler** - Aptapharma Inc. (790523323)**Registrant** - Aptapharma Inc. (790523323)**Establishment**

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(76281-302)

Revised: 10/2019

Aptapharma Inc.