

**CHILDRENS PAIN AND FEVER- acetaminophen suspension**  
**AptaPharma Inc.**

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**Children's Pain & Fever Grape Flavor**

***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

**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 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.

**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 (Children's Pain & Fever)**

- 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.

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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)

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\*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.

**Directions (Infants' Pain Relief)**

- **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)*
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 dosing syringe 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

■ **Keep carton for full directions for use.**

**Inactive ingredients** anhydrous citric acid, butylparaben. D&C Red #33. FD&C Blue #1. 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**

**AP SAFE®**

**NDC 76821-526-24**

**COMPARE TO THE**

**ACTIVE INGREDIENT IN**

**CHILDREN'S TYLENOL®**

**ORAL SUSPENSION\***

**Children's**

**Pain**

**& Fever**

**Acetaminophen**

**Oral Suspension**

**Pain reliever/Fever Reducer**

- **Alcohol-Free**
- **Ibuprofen Free**
- **Aspirin Free**
- **For Ages 2 to 11**

**4 FL OZ (118 mL)**

**160 mg per 5 mL**

**Grape Flavor**

**DO NOT USE IF PRINTED NECK BAND IS  
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

**AP-BX-06**

Carton

DO NOT USE IF PRINTED NECK BAND 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  
**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ 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**  
■ 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 ▶

**AP SAFE**®      NDC 76281-526-24

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

**Children's Pain & Fever**  
Acetaminophen Oral Suspension

**Pain Reliever  
Fever Reducer**

- Alcohol Free
- Ibuprofen Free
- Aspirin Free
- For Ages 2 to 11

 Grape Flavor

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

**Drug Facts (continued)**

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
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  
■ keep carton for full directions for use.

**Inactive ingredients** anhydrous citric acid, butylparaben, D&C Red # 33, FD&C Blue # 1, 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

**AP-BX-06**

**AP SAFE**®      NDC 76281-526-24

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

**Children's Pain & Fever**  
Acetaminophen Oral Suspension

**Pain Reliever  
Fever Reducer**

- Alcohol Free
- Ibuprofen Free
- Aspirin Free
- For Ages 2 to 11

 Grape Flavor

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



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Bottle



NDC 76281-526-24

Children's

# Pain & Fever

Acetaminophen  
Oral Suspension

Pain Reliever  
Fever Reducer

- Alcohol Free
- Ibuprofen Free
- Aspirin Free
- For Ages 2 to 11

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



Grape Flavor

### DO NOT USE IF PRINTED NECK BAND 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 **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 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 ■ 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 **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, D&C Red # 33, FD&C Blue # 1, 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: AptA Pharma Inc.,

1533 Union Ave. Pomona, NJ 08110 AP-LR-18 EXP:

Carton

No Coating Area

# Infants' Pain Relief

Acetaminophen Oral Suspension - 160 mg per 5 mL

Pain Reliever - Fever Reducer

DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING.

### 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
    - teething

#### 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)

#### Step 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**  
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
- 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.

Dosing Chart		
Weight (lb)	Age (yr)	Dose (mL)**
Under 24	Under 2 years	Ask a doctor
25-35	2-3 years	5 mL

\*or as directed by **Atlixia**: use only enclosed dosing syringe specifically designed for use with this product. Do not use any other dosing device.

#### Other information

- each 5 mL contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients** anhydrous citric acid, butylparaben, D&C Red # 33, FD&C Blue # 1, 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 1-877-798-6944

AP-8X-15  
Manufactured by: AptoPharma Inc.,  
1033 Union Ave., Pennington, NJ 08110  
\*\* This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Oral Suspension.

NDC 7081-58-23



Compare to Infants' TYLENOL® Oral Suspension active ingredient\*\*

# Infants' Pain Relief

Acetaminophen Oral Suspension - 160 mg per 5 mL

Pain Reliever  
Fever Reducer

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

2 FL. OZ (59 mL)



Grape Flavor

### IMPORTANT INSTRUCTIONS

- Remove the cap.
- Insert the syringe tip through the opening at the top of the bottle.
- Turn the bottle upside down and fill syringe to dose.

Use enclosed syringe only. Do not use other dosing devices.



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Glue

No Coating Area

LOT:

EXP:

Non-Varnish

Bottle

**AP SAFE**® NDC 76281-526-23

**Infants' Pain Relief**  
Acetaminophen Oral Suspension - 160 mg per 5 mL

**Pain Reliever  
Fever Reducer**

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

**IMPORTANT:**  
Use enclosed syringe ONLY. DO NOT USE other dosing devices.  
2 FL OZ (59 mL) Grape Flavor

**DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING.**

**Drug Facts**

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

Use 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.

**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.

**See 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: In case of overdose, get medical help or contact LOT.

**EXP.**

**PEEL HERE**

Manufactured by: AptiaPharma Inc.,  
1533 Union Ave., Pennsauken, NJ 08110 AP-LR-30

**Reseal Area**

**Drug Facts (continued)**

**Caution:** Keep out of reach of children. If swallowed, quickly get medical attention. If you do not notice any signs or symptoms in 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. ■ 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.

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

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

**Other information**

- each 5 mL contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients:** acetylsalicylic acid, butylparaben, DAC Red # 33, FD&C Blue # 1, ferrous glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, saccharin, xanthan gum.

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

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## CHILDRENS PAIN AND FEVER

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76281-526
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) ACETAMINOPHEN 160 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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 SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-526-24	1 in 1 CARTON	09/30/2020	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:76281-526-23	1 in 1 CARTON	01/30/2024	
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	08/21/2013	

**Labeler** - AptaPharma Inc. (790523323)

**Registrant** - AptaPharma Inc. (790523323)

**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-526)

Revised: 2/2024

AptaPharma Inc.