

CHILDRENS PAIN AND FEVER- acetaminophen suspension
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.

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

- 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
- Keep carton for full directions for use.

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**

Product Label

AP SAFE®

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

Cherry Flavor

DO NOT USE IF PRINTED NECK BAND IS
BROKEN OR MISSINGThis

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

2 OZ PACKAGE

No Coating Area

Glue

No Coating Area

Infants' Pain Relief

Acetaminophen
Oral Suspension - 160 mg per 5 mL
Pain Reliever - Fever Reducer

AP SAFE

Compare to Infant Tylenol Oral Suspension active ingredient**

Infants' Pain Relief

Acetaminophen
Oral Suspension - 160 mg per 5 mL

**Pain Reliever
Fever Reducer**

Use ONLY enclosed syringe

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

2 FL. OZ. (59 mL) Cherry Flavor

NDC 15281-525-23

IMPORTANT INSTRUCTIONS

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

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

No Coating Area

Non-Varnish

Drug Facts (continued)

Directions

- This product does not contain dextrose or complete warnings for adult use.
- Shake well before using.
- 1 mL = 1 milliliter
- First right dose on chart below. If possible, use weight to dose; if available, use age.
- If needed, repeat dose every 4 hours while symptoms last.
- Do not give more than 5 doses 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	1 mL

*Or as directed by healthcare provider. 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)
- See other information

Inactive ingredients hydroxyethylcellulose, hydroxypropylcellulose, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxypropylcellulose and calcium hydroxylaluminum sulfate, propylene glycol, purified water, sorbitol, sodium benzoate, sodium citrate, sodium phosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sucrose, xanthan gum.

Questions? Call us anytime from 9:00 AM to 4:00 PM EST at 1-877-238-9242

AP-SAFE-06
Manufactured by ApolPharma Inc., 1337 Green Ave., Pennington, NJ 08119
**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infant Tylenol Oral Suspension.

Reseal Area

Drug Facts (continued)

© Pediatric Control Center, Inc. (1-800-222-1222)
Do not use this product on children for adults as well as for children unless you have been advised by a doctor.

Directions ■ This product does not contain dextrose or complete warnings for adult use. ■ Shake well before using. ■ 1 mL = 1 milliliter ■ First right dose on chart below if possible, use weight to dose; if available, use age. ■ If needed, repeat dose every 4 hours while symptoms last. ■ Do not give more than 5 doses 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	1 mL

*Or as directed by healthcare provider. 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)
- See other information

Inactive ingredients hydroxyethylcellulose, hydroxypropylcellulose, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxypropylcellulose and calcium hydroxylaluminum sulfate, propylene glycol, purified water, sodium benzoate, sodium phosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sucrose, xanthan gum.

Questions? Call us anytime from 9:00 AM to 4:00 PM EST at 1-877-238-9242

AP SAFE

Compare to Infant Tylenol Oral Suspension active ingredient**

Infants' Pain Relief

Acetaminophen
Oral Suspension - 160 mg per 5 mL
Pain Reliever - Fever Reducer

Use ONLY enclosed syringe

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

2 FL. OZ. (59 mL) Cherry Flavor

NDC 15281-525-23

IMPORTANT INSTRUCTIONS

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

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

Drug Facts

Active ingredient (in each 5 mL) Purpose
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.

Be very 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.

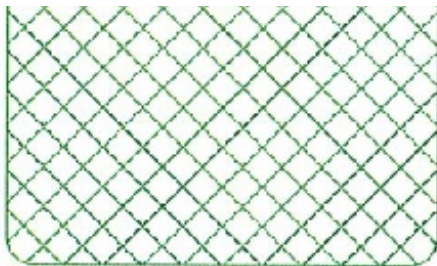
Severe throat warning: If severe throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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 if you are taking or have taken your child is taking the blood thinning drug warfarin.

When using this product do not exceed recommended dose (see directions).



OVERDOSE WARNING:
 Stop use and ask doctor if: ■ pain gets worse or lasts more than 3 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:
 Manufactured by: AptaPharma Inc.,
 1533 Union Ave., Pennsauken, NJ 08110 AP-LR-27

PEEL HERE

4 OZ PACKAGE

Carton

NDC 76281-525-24

DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

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

Cherry Flavor

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

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 reddening
 ■ hives ■ 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 is**

NDC 76281-525-24

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

Cherry Flavor

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

Drug Facts (continued)
 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 (lbs)	Age (yrs)	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 (1.5 tsp)
48-59	6-7 years	10 mL (2 tsp)
60-71	8-10 years	12.5 mL (2.5 tsp)
72-85	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, dicyclanil, 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 1-877-758-5944

*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-01 Rev. 01

NDC 76281-525-24

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

Cherry Flavor

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

3 76281 52524 3

Bottle



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, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, saccharose, xanthan gum
Questions? Call 1-877-798-5944 **LOT:**

Manufactured by: AptaPharma Inc.,
 1533 Union Ave, Pennsauken, NJ 08110 **EXP:**
 AP-LR-01 Rev. 01

res

CHILDRENS PAIN AND FEVER
 acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-525
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: 3QPI1U3FV8)	
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 SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-525-24	1 in 1 CARTON	09/30/2020	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:76281-525-23	1 in 1 CARTON	09/30/2020	
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 not			

OTC monograph not final	part343	08/21/2013	
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Labeler - Aptapharma Inc. (790523323)

Registrant - Aptapharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(76281-525)

Revised: 1/2023

Aptapharma Inc.