

CHILDRENS PAIN AND FEVER- acetaminophen suspension
AptaPharma Inc.

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



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. **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 rash/itching
- hives
- itch

If a skin reaction occurs, stop use and seek medical help right away.
Severe throat warning: If your child's fever, 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:

- your child vomits or has more than 5 days
- your child 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 (1-800-332-1122). **Severe 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

- Use as directed. Do not contain dextrose or complete warnings for adult use.
- Shake well before using.
- 1 mL = 1 milliliter.
- First night dose on chart below, if possible, use weight to dose; at bedtime, 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.

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

*Or as directed by healthcare 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: ethylhexyl salicylate, hydroxybenzofluorenone, FDAC red #40, flavor, glycerin, light hydrophobic emulsifier, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum.

Questions? Call weekdays from 9:30 AM to 4:30 PM CST at 1-877-268-9344.

AP-005-09
Manufactured by: ApixPharma Inc., 1537 Green Ave., Phoenix, AZ 85019
**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infant's Tylenol® Oral Suspension.

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.

Use ONLY enclosed syringe.

• Alcohol Free
• Aspirin Free
• Ibuprofen Free

Cherry Flavor

2 FL. OZ. (59 mL)

3 76281 52523 6

Non-Coating Area

Non-Varnish

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

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

Drug Facts (continued)
Directions

- Use as directed. Do not contain dextrose or complete warnings for adult use.
- Shake well before using.
- 1 mL = 1 milliliter.
- First night dose on chart below, if possible, use weight to dose; at bedtime, 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.

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

*Or as directed by healthcare 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: ethylhexyl salicylate, hydroxybenzofluorenone, FDAC red #40, flavor, glycerin, light hydrophobic emulsifier, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum.

Directions? Call weekdays from 9:30 AM to 4:30 PM CST at 1-877-268-9344.

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.

Use ONLY enclosed syringe.

• Alcohol Free
• Aspirin Free
• Ibuprofen Free

Cherry Flavor

2 FL. OZ. (59 mL)

3 76281 52523 6

Drug Facts
Active ingredient (in each 5 mL): 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 rash/itching
- hives
- itch

If a skin reaction occurs, stop use and seek medical help right away.
Severe throat warning: If your child's fever, 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:

- your child vomits or has more than 5 days
- your child 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

Reseal Area



EXP:

Manufactured by: AzaPharma Inc.,
1533 Union Ave., Pennsauken, NJ 08110

AP-LR-27

PEEL HERE



4 OZ PACKAGE

Carton



Bottle

AP SAFE®
NDC 76281-525-24

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

Cherry 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 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 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)*
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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

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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 Drug	M013	08/21/2013	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

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

Revised: 12/2024

AptaPharma Inc.